

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-K

**ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

**TRANSITION REPORT PURSUANT TO SECTION 13 OF 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 0-22613

AVI BIOPHARMA, INC.

(Name of small business issuer in its charter)

Oregon

(State or other jurisdiction of incorporation
or organization)

93-0797222

(I.R.S. Employer Identification No.)

One SW Columbia Street, Suite 1105, Portland, Oregon

(Address of principal executive offices)

97258

(Zip Code)

Issuer's telephone number, including area code: **503-227-0554**

Securities registered under Section 12(b) of the Exchange Act: **None**

Securities registered under Section 12(g) of the Exchange Act:

Common Stock with \$.0001 par value

(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes No .

The aggregate market value of the voting stock held by non-affiliates of the Registrant (based on the closing sale price of the Common Stock as reported on the Nasdaq Stock Market on June 30, 2003) was approximately \$162,020,784 as of June 30, 2003. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of the close of business on March 12, 2004 was 36,093,235.

Documents Incorporated by Reference

The issuer has incorporated into Part III of Form 10-K, by reference, portions of its Proxy Statement for its 2004 annual meeting.

AVI BIOPHARMA, INC.

FORM 10-K INDEX

PART I

[Item 1.](#) [Description of Business](#)

[Item 2.](#) [Description of Property](#)

[Item 3.](#) [Legal Proceedings](#)

[Item 4. Submission of Matters to a Vote of Security Holders](#)

PART II

[Item 5. Market for Common Equity and Related Stockholder Matters](#)

[Item 6. Selected Financial Data](#)

[Item 7. Management's Discussion and Analysis or Plan of Operation](#)

[Item 7A. Quantitative and Qualitative Disclosures About Market Risk](#)

[Item 8. Financial Statements](#)

[Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure](#)

[Item 9A. Controls and Procedures](#)

PART III

[Item 10. Directors and Executive Officers of the Registrant](#)

[Item 11. Executive Compensation](#)

[Item 12. Security Ownership of Certain Beneficial Owners and Management](#)

[Item 13. Certain Relationships and Related Transactions](#)

[Item 14. Principal Accountant Fees and Services](#)

[Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K](#)

[Signatures](#)

1

PART I

Item 1. Description of Business

General Overview

We are a biopharmaceutical company developing therapeutic products principally based on third-generation NEUGENE[®] antisense technology. Our principal products in development target life-threatening diseases, including cardiovascular disease, infectious disease and cancer. Currently approved drugs or other therapies for these diseases often prove to be ineffective or produce undesirable side effects. Our pre-clinical and clinical studies indicate that our technology may produce drugs that we believe offer more effective treatment options with fewer side effects than currently approved products. A patent estate including 138 patents (foreign and domestic) issued or licensed to us and 130 pending patent applications (domestic and foreign) protects our technologies. Our lead product candidate, Resten-NG[®], targets a market we believe may exceed \$1 billion worldwide.

We have developed third-generation antisense technology that we believe produces drugs that may be more stable, specific, efficacious, and cost effective than other gene-targeting technologies, including second-generation antisense, ribozyme, and siRNA compounds. In eleven clinical trials involving 242 patients, we have not observed a single drug-related serious adverse event. NEUGENE drugs are synthetic polymers that block the function of selected genetic sequences involved in disease processes. Targeting specific genetic sequences provides for greater selectivity than that available through conventional drugs. NEUGENE drugs have the potential to provide safe and effective treatment for a wide range of human diseases. Our NEUGENE drugs are distinguished by a novel backbone chemistry that replaces the modified backbones of competing technologies with a synthetic backbone that has been designed to improve pharmaceutical parameters.

We have completed pre-clinical and some clinical studies using our NEUGENE drugs in the treatment of cardiovascular disease, infectious disease, cancer and polycystic kidney disease (PKD), and in regulating drug metabolism. We filed our first antisense Investigational New Drug application (IND) with the FDA for Resten-NG for cardiovascular restenosis in 1999 and have completed a Phase I substantially completed a Phase II clinical trial. We have completed four Phase I trials in our drug metabolism program and two Phase Ib trials in our cancer and polycystic kidney disease programs. We filed an IND and conducted a Phase Ib trial in 2003 for our NEUGENE antisense drug for West Nile virus infection.

AVICINE, a therapeutic cancer vaccine, is based on a second technology that we utilize in our cancer program. It represents an advanced product opportunity. We have substantially completed six human clinical trials for AVICINE, including multi-center Phase II trials for colorectal cancer and pancreatic cancer. Cancer vaccines operate under the rationale that immunization stimulates an immune response that is effective in combating an existing cancer. AVICINE stimulates an immune response against a hormone that is expressed on most cancers and is believed to promote the growth and spread of cancer. This hormone, human chorionic gonadotropin (hCG), is normally responsible for stimulating fetal development during pregnancy, but is also associated with major types of cancer, including colon, pancreatic, prostate, lung, and breast.

Based on our AVICINE clinical trials involving 174 patients with advanced stages of cancer, we believe that this vaccine has a modest toxicity profile compared to other cancer therapies

2

and is capable of producing a specific immune response in most patients. Further, the patients who mounted an immune response to vaccination appeared to derive a survival benefit. We intend to investigate further the use of AVICINE alone and in combination with other approved therapies in additional Phase II trials for pancreatic cancer and, with the addition of an appropriate partner, Phase III trials.

This annual report includes our trademarks and registered trademarks, including NEUGENE, AVICINE, Resten-NG and Oncomyc-NG. Each other trademark, trade name or service mark appearing in this annual report belongs to its holder.

Clinical Development Program

Our therapeutic products are based on NEUGENE antisense technology with initial applications in cardiovascular disease, infectious disease, and cancer, and based on our AVICINE vaccine with applications in cancer. We currently have products at various stages of clinical development as summarized below. We will not have marketable products unless and until our drug candidates complete all required clinical trials and receive FDA approval in the United States or approval by regulatory agencies outside of the United States.

Product Candidate	Type	Pre-Clinical	Phase I/Ib	Phase II	Phase III
Cardiovascular Disease					
Restenosis: Resten-NG	NEUGENE Drug	Completed	Completed	Completed	Planned
Restenosis: Resten-MP microparticles	NEUGENE Drug	Completed	Completed	In-progress	
CABG: AVI-4526-CP5	NEUGENE Drug	In-progress	Planned		
CABG: Resten-MP	NEUGENE Drug	In-progress			
Infectious Disease (Viral targets)					
West Nile: AVI-4020	NEUGENE Drug	Completed	Completed		
Hepatitis C: AVI-4020	NEUGENE Drug	In-progress	Planned		
SARS: AVI-4179	NEUGENE Drug	Completed			
Dengue Virus	NEUGENE Drug	In-progress			
Cancer					
Pancreatic: AVICINE	Cancer Vaccine	Completed	Completed	Completed	
Colorectal: AVICINE	Cancer Vaccine	Completed	Completed	Completed*	
Cancer: Oncomyc-NG™	NEUGENE Drug	Completed	Completed		
Lung: Oncomyc-NG	NEUGENE Drug	Completed			
Prostate	NEUGENE Drug	In-progress			
Drug Metabolism					
Cytochrome P450: AVI-4557	NEUGENE Drug	Completed	Completed		
Genetic Disorders					
PKD: AVI-4126	NEUGENE Drug	Completed	Completed	Planned	

In this table, “Planned” refers to trials that are being designed although a protocol may not yet be complete; “In-progress” refers to studies or trials that have actively begun but are not yet complete; and “Completed” refers to studies in which the clinical trial or study has ended, the data have substantially been collected and validated, and a full study report is either in progress or complete.

* A Phase III trial in colorectal cancer is not anticipated. We have selected pancreatic cancer for an additional Phase II trial due to considerations of cost, timeline and study design. If we secure an appropriate partner with whom to share the costs of a Phase III program, we would anticipate moving into a Phase III clinical trial in the future.

Costs for a clinical trial typically range between \$300,000 and \$500,000 for a Phase I trial, between \$500,000 and \$4 million for a Phase II trial and could range between \$5 and \$50 million for a Phase III trial. Because the scope, timing and issues encountered in each trial vary, we cannot predict the exact costs associated with a particular trial in advance. For the

same reasons, we cannot predict the nature, timing and costs of future studies or trials for a product, how a product will proceed toward and through Phase III clinical trials and, if Phase III clinical trials are successful, when and if FDA approval will be sought and received.

Cardiovascular Disease Program. Resten-NG is a NEUGENE antisense drug for treating cardiovascular restenosis, or the re-narrowing of a coronary artery following angioplasty. Resten-NG targets a key regulatory gene involved in the disease process. We believe that by blocking the action of this gene, the

occurrence of vessel wall re-narrowing will be reduced or eliminated. A nonexclusive license has been granted to Medtronic, Inc. for our antisense compounds deployed on stents or certain other devices for treating restenosis. At the September 2003 Transcatheter Cardiovascular Therapeutics conference, we announced interim Phase II clinical trial data showing that Resten-NG delivered via catheter during balloon angioplasty procedures resulted in an approximate 75% reduction in the restenosis rate. At the April 2003 American College of Cardiology meeting, results from two independent studies were presented that additionally demonstrate the potential of treating cardiovascular restenosis by delivering Resten-NG systemically using our proprietary microparticle delivery technology, possibly lessening the need for, or as an adjunct to, use of special drug delivery catheters or drug-coated stents. We have initiated a Phase II clinical trial with Resten-NG coupled with our microparticle delivery technology at the University of Nebraska Medical Center. We are planning a Phase III trial to be initiated in the first half of 2004 in Europe for Resten-NG delivered on a stent platform with a partner to meet the regulatory requirements for a CE Mark, constituting marketing approval for the European Union.

Infectious Disease Program. Our infectious disease program is currently focusing on single-stranded RNA viruses using our proprietary NEUGENE antisense agents targeting West Nile virus, Hepatitis C virus, Dengue virus, and the SARS coronavirus, and also targeting many of the viruses included on the Domestic Homeland Security list of bioterrorism viruses. In May 2003, we filed an application with the FDA to obtain Orphan Drug designation for our West Nile NEUGENE drug candidate, AVI-4020, and submitted an IND the following month. Our NEUGENE drug candidate AVI-4179, designed to combat the SARS coronavirus, has been evaluated at an independent laboratory and found to be efficacious in pre-clinical studies. Phase Ib clinical trials in West Nile virus are currently underway. We have filed for Orphan Drug designation for our SARS coronavirus drug candidate, as well. Due to unpredictable future demand for drugs targeting West Nile virus and the SARS coronavirus, our future clinical development in viral diseases will initially focus on Hepatitis C and Dengue virus.

Cancer Program. We have completed a Phase Ib clinical trial with our NEUGENE drug candidate AVI-4126, which demonstrated the systemic delivery into solid tumor tissues for both breast and prostate cancer patients. AVI-4126 targets the oncogene c-myc. Over-expression of c-myc has been described in many types of cancers. We plan to conduct a multiple dosing study with AVI-4126 early in 2004 and a Phase Ib clinical trial in cancer later in 2004. In January 2003, we were awarded a \$250,000 grant from the National Cancer Institute to target prostate cancer. We plan to initiate an additional Phase Ib clinical study with an additional NEUGENE antisense agent in 2004.

In June 2000, we reported Phase II data demonstrating that AVICINE provided a survival benefit to patients with late-stage colorectal cancer who responded to the vaccine. Published studies indicate that patients that had a strong antibody response to the vaccine had a higher median survival than patients that had a weak antibody response, or than patients treated with chemotherapeutic drugs. These results were presented in May 2001 at the American Society of Clinical Oncology (ASCO) meeting and published in July 2002 in *Cancer Research*, a publication of the American Association for Cancer Research.

5

In December 2001, we reported Phase II data demonstrating that AVICINE provided a survival benefit to patients with pancreatic cancer. In this study, patients were treated with AVICINE alone, or with AVICINE in combination with the chemotherapeutic agent Gemzar®. A one-year survival rate of 30% was reported for patients treated with AVICINE plus Gemzar, which is approximately double the survival rate for either treatment alone. In May 2002, we presented complete survival data from the Phase II pancreatic cancer study at the ASCO meeting. This data confirmed and extended the positive results reported previously in our Phase II study in colorectal cancer. We plan to begin an additional Phase II clinical program with AVICINE for treating pancreatic cancer in the first half of 2004. SuperGen, Inc. (SuperGen) is an exclusive partner with us in the development and commercialization of AVICINE in the United States, and we are seeking an appropriate partner with whom to share costs of a Phase III program.

Drug Metabolism Program. We have successfully completed clinical trials demonstrating that our NEUGENE antisense drug improved the pharmacokinetic profile of two different test drugs by down-regulating the liver enzyme that is critical to the body's processing of many drugs. Two clinical studies completed in late 2002 showed that AVI-4557 down-regulated cytochrome P450 3a4, which resulted in an improved pharmacokinetic profile of the test drugs. In September 2003, we initiated an oral dosing study with this agent to evaluate the oral route of administration for our antisense compounds. This study is substantially complete. Additional Phase II trials will be designed after establishing strategic relationships with pharmaceutical co-development partners.

Polycystic Kidney Disease Program. We completed a Phase Ib clinical trial in 2002 to evaluate the safety and pharmacokinetics of three doses of AVI-4126 in adult patients with polycystic kidney disease and with varying degrees of compromised kidney function. Results of the study showed an excellent safety profile and no adverse effect on kidney function. We are designing a Phase II clinical study in the early onset form of PKD that is usually lethal for children. This form of PKD is very similar genetically to the pre-clinical PKD models that we have used to produce efficacy data for our antisense drug. We expect to initiate this trial in the second half of 2004.

Business Strategy

Our strategy is to:

- reduce risk associated with product development by exploiting two core technologies;
- select gene targets with broad or multiple disease applications;
- manage drug discovery, pre-clinical and early to mid-stage clinical development in-house; and
- initially co-develop or license products to strategic partners during or after completion of Phase II clinical trials to enhance value and share the costs of late stage clinical trials and commercialization.

Collaborative Agreements

We believe that our NEUGENE and cancer vaccine technologies are broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To exploit our core technologies as fully as possible, we expect to enter into collaborative development agreements with pharmaceutical companies for all cancer applications with our vaccine, and agreements directed at specific molecular targets for our NEUGENE antisense technology.

6

We anticipate that the NEUGENE antisense collaborative research agreements may provide us with some funding for internal programs aimed at discovering and developing antisense compounds to inhibit the production of additional molecular targets. Partners in antisense may be granted options to obtain licenses to co-develop and to market drug candidates resulting from their collaborative research programs. We intend to retain manufacturing rights to our antisense products. There can be no assurance, however, that we will be able to enter into collaborative research agreements with pharmaceutical companies on terms and conditions satisfactory to us. The agreements described in this “Collaborative Agreements” section are generally only cancelable for nonperformance, including failure to make any payments and, in some cases, failure to commercially exploit the technology. There is no assurance the proposed products will be successfully developed under these collaborative arrangements or we will receive any of the potential payments noted herein.

SuperGen Alliance

In April 2000, we entered into an alliance with SuperGen, Inc. for shared development and marketing rights for AVICINE. Under the terms of the agreement, SuperGen and AVI will share equally clinical development and FDA registration costs going forward and share profit equally from product sales in the United States. Our share of such costs are expected to approximate \$10 million over the next two to three years and up to \$15 million in the aggregate with development expected to take at least three to four years. We will be responsible for the manufacturing of AVICINE and SuperGen will be responsible for marketing and sales. In May 2000, we received a \$20 million equity investment from SuperGen and could receive additional payments of up to \$80 million based upon achievement of clinical commercialization milestones. Those payments include the following milestone payments, plus certain payments based on product sales (i) \$2.5 million in SuperGen stock or cash, upon each completion of a Phase III trial for the pharmaceutical product containing AVICINE or a derivative thereof as an active ingredient and acceptance by the FDA or New Drug Application (“NDA”) and (ii) \$5 million in SuperGen stock or cash, upon the date the first commercial sale of a pharmaceutical product containing AVICINE or a derivative thereof as an active ingredient occurs within the United States. Commercialization cash milestone payments occur at the following annual sales levels: \$100 million, \$250 million, \$500 million and \$1 billion. Payments to AVI occur at the first achievement of these sales levels and increase from \$10 million to \$25 million in \$5 million increments, with a maximum of one milestone payment per year.

Unless terminated earlier, our agreement with SuperGen expires upon the earlier of (i) the date upon which a generic version of the product is first sold in the U.S. by someone other than SuperGen or (ii) the date which is 15 years after the date of regulatory approval of AVICINE in the United States, subject to certain extension rights.

NEUGENE Alliances

We anticipate that NEUGENE antisense collaborative research agreements may provide us with funding for internal programs aimed at discovering and developing antisense compounds to inhibit the production of additional molecular targets. Partners in antisense may be granted options to obtain licenses to co-develop and to market drug candidates resulting from their collaborative research programs. We currently have a research alliance with XTL Biopharmaceuticals Ltd. for pre-clinical development of Hepatitis B and C antisense drugs. If this program moves into clinical development stages, XTL and we will negotiate a joint venture development and marketing agreement with XTL under basic terms previously set forth, or we will negotiate a licensing arrangement with a third party. We do not believe that these agreements will obligate us to spend any particular amounts in exploiting products. We expect to expend approximately \$3 million on clinical development efforts over the next two years related to these products.

Exelixis Agreement

In April 2001, we entered into an alliance with Exelixis Inc. (“Exelixis”) for functional genomics and antisense drug development. Under the terms of the agreement, Exelixis will apply its expertise in genetic model systems to discover, validate and screen novel targets suitable for inhibition by antisense therapeutics. We will design and synthesize NEUGENE morpholinos (PMOs) for use as drugs and conduct preclinical and clinical studies on antisense drug candidates arising from the collaboration. We expect to expend approximately \$2 million over the next two years in developing products under the agreement and up to \$10 million in the aggregate. The collaborative research project and our obligations to supply PMOs to Exelixis under the agreement expires April 30, 2006. Except as noted, we and Exelixis will jointly own, and Exelixis has an option to co-develop with us, certain antisense products that arise from the alliance.

In the event we and Exelixis co-fund the development of any antisense therapeutic and/or commercialization of any product, the parties will jointly have a worldwide, co-exclusive license and will equally share profits with respect to any such co-funded product in lieu of royalties. Product is defined by our agreement with Exelixis as any human therapeutic or prophylactic product which received regulatory approval that contains or comprises our antisense therapeutic.

Under our agreement with Exelixis, an “Exelixis Product” is defined as, and is deemed to exist when we decide to terminate the development of a co-funded antisense therapeutic and/or commercialization of a particular co-funded product that is being co-funded by Exelixis, and Exelixis assumes the costs and obligations of the continued development of the co-funded antisense therapeutic and/or commercialization of such co-funded product (Exelixis Product”). Similarly, an AVI product is one that is developed by us and not co-funded by Exelixis (“AVI Product”).

Generally, a 3% or 5% royalty on net sales is payable by the developing party on products covered by the agreement that are not jointly developed.

Generally, a party’s right to receive royalties expires on a country-by-country basis upon the later of (i) 12 years from the first commercial sale of such product in that country; or (ii) expiration of the last to expire Exelixis patent or AVI patent in such country claiming the antisense therapeutic in such AVI product or the manufacture, use or sale of such product.

Medtronic Agreement

In May 2001, we entered into a licensing arrangement with Medtronic, Inc. (“Medtronic”) wherein Medtronic received exclusive rights for certain antisense compounds, for use in conjunction with Medtronic devices, to combat vascular disease, including restenosis. We also entered into a supply agreement to provide product to Medtronic. Under an investment agreement, we received a \$10 million equity investment from Medtronic International, Ltd. (then Medtronic Asset Management, Inc.) (“MIL”). In 2003, we elected to convert Medtronic’s license to non-exclusive. We have some ongoing obligations under the various agreements as to assisting Medtronic in developing its product and manufacturing the product when developed.

We plan to market the initial products for which we obtain regulatory approval, through co-development and marketing arrangements with strategic partners such as Medtronic or other licensing arrangements with larger pharmaceutical companies. Implementation of this strategy will depend on many factors, including the market potential of any products we develop and our financial resources. We do not expect to establish a direct sales capability for therapeutic compounds for at least the next several years. The timing of our entry into

marketing arrangements or other licensing arrangements will depend on successful product development and regulatory approval within the regulatory framework established by the Federal Food, Drug and Cosmetics Act. Although the implementation of initial aspects of our marketing strategy may be undertaken before this process is completed, the development and approval process typically is not completed in less than three to five years after the filing of an IND application and our marketing strategy therefore may not be implemented for several years.

Manufacturing

We believe we have developed proprietary manufacturing techniques that will allow large-scale synthesis and purification of NEUGENES. Because our NEUGENE compounds are based upon a flexible backbone chemistry, we believe that NEUGENE synthesis will be more cost-effective than competing technologies. We have established a Good Manufacturing Practices, or GMP, manufacturing facility at our Corvallis, Oregon facility. Our GMP facility should provide sufficient manufacturing capacity to continue to meet our early stage clinical trial requirements for the foreseeable future and allow us to produce products incorporating our technology. Our GMP facility is subject to FDA inspection and regulation.

We currently intend to retain manufacturing rights for all products incorporating our patented antisense technology, whether sold directly by us or through collaborative agreements with industry partners. We have also contracted with GMP facilities to produce our vaccine for current clinical trial studies.

In March 1993, we moved to our present laboratory facilities. This facility and the laboratory procedures followed by us have not been formally inspected by the FDA and will have to be approved as products move from the research phase through the clinical testing phase and into commercialization. See “Drug Approval Process and Other Governmental Regulations.”

Marketing Strategy

We plan to market initial products, when developed, and for which we obtain regulatory approval, through marketing arrangements or other licensing arrangements with pharmaceutical companies. Implementation of this strategy will depend on many factors, including the market potential of any products we develop, and our financial resources. We do not expect to establish a direct sales capability for therapeutic compounds for at least the next several years. To market products that will serve a large, geographically diverse patient population, we expect to enter into licensing, distribution, or partnering agreements with pharmaceutical companies that have large, established sales organizations. The timing of our entry into marketing arrangements or other licensing arrangements with large pharmaceutical companies will depend on successful product development and regulatory approval within the regulatory framework established by the Federal Food, Drug and Cosmetics Act, as amended, and regulations promulgated thereunder. Although the implementation of initial aspects of our marketing strategy may be undertaken before this process is completed, the development and approval process typically is not completed in less than three to five years after the filing of an IND application and our marketing strategy therefore may not be implemented for several years. See “Drug Approval Process and Other Governmental Regulation.”

Patents and Proprietary Rights

We have developed or acquired a comprehensive body of intellectual rights. The proprietary nature of, and protection for, our product candidates, processes and know-how are important to our business. We plan to prosecute and aggressively defend our patents and proprietary

technology. Our policy is to patent the technology, inventions, and improvements that are considered important to the development of our business and that are patentable. We also depend upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position.

A patent estate including 138 patents (domestic and foreign) issued or licensed to us, and 130 pending patent applications (domestic and foreign) protects our technologies. We intend to protect our proprietary technology with additional filings as appropriate. Some of our patents on core technologies expire as early as 2008, including for NEUGENES; however, based on patented improvements and additional support to such core patents, we believe our patent protection for those products and other products will extend beyond 2020.

We have also acquired certain product/technology licenses from The Ohio State University and Dr. Vernon Stevens. These licenses include exclusive royalty-bearing licenses covering the composition, manufacturing and use of AVICINE in all fields of use, including treating and preventing cancer, with the exception of fertility regulation. Our proprietary rights also include the unrestricted use of vaccine technology for non-hormonal cancer applications. We enjoy the right to commercialize any new intellectual property relating to our licensed subject matter, including access to and use of all new experimental data resulting from Dr. Stevens’ research. Our licenses have been granted for a period of 30 years or 10 years from the expiration of the last issued patent, whichever comes later. Under these licensing agreements, we have the right to sublicense our products and technology throughout the world. For such rights, we are obligated to pay the licensors minimum annual royalties of \$55,000. Subject to such minimums, the royalties are 5% of net sales of products from licensed technology in the United States and Canada; 2% of net sales in countries of the “European Economic Community”; and 25% of any royalties received by us for sublicenses in the United States, the “European Economic Community” or in Korea, subject to certain maximums.

We have licensed certain technology from the Public Health Service (and others) to technology supplement and support certain of our core technology. We have certain obligations and minimum royalties under those agreements, which costs are not deemed material to our business.

There can be no assurance that any patents we apply for will be granted or that patents held by us will be valid or sufficiently broad to protect our technology or provide a significant competitive advantage. Additionally, we cannot provide assurance that practice of our patents or proprietary technology will not infringe third-party patents.

Drug Approval Process and Other Government Regulation

The United States system of new drug approvals is the most rigorous in the world. According to the Pharmaceutical Research and Manufacturers of America, it costs an average of \$500 million and takes an average of almost 15 years from the discovery of a compound to bring a new pharmaceutical to market. For every 5,000 to 10,000 chemically synthesized molecules screened, only 250 are ever issued an IND for testing in humans and only one will obtain FDA approval.

Drug Discovery

In the initial stages of drug discovery before a compound reaches the laboratory, tens of thousands of potential compounds are randomly screened for activity against an assay assumed to be predictive for particular disease targets. This drug discovery process can take several years. Once a company locates a screening lead, or starting point for drug development, isolation and structural determination may begin. The development process

10

results in numerous chemical modifications to the screening lead in an attempt to improve its drug properties. After a compound emerges from the above process, the next steps are to conduct further preliminary studies on the mechanism of action, further in vitro (test tube) screening against particular disease targets and, finally, some in vivo (animal) screening. If the compound passes these barriers, the toxic effects of the compound are analyzed by performing preliminary exploratory animal toxicology. If the results are positive, the compound emerges from the basic research mode and moves into the pre-clinical phase.

Preclinical Testing

During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests typically take approximately three and one-half years to complete.

Investigational New Drug Application

During the pre-clinical testing, an IND is filed with the FDA to begin human testing of the drug. The IND becomes effective if not rejected by the FDA within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. In addition, an Institutional Review Board, comprised of physicians at the hospital or clinic where the proposed studies will be conducted, must review and approve the IND. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA.

Phase I Clinical Trials

After an IND becomes effective, Phase I human clinical trials may begin. These tests, involving usually between 20 and 80 patients or healthy volunteers, typically take approximately one year to complete and cost between \$300,000 and \$500,000 per trial. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. Phase I trials are not normally conducted for anticancer product candidates. A phase Ib study involves patients with the targeted disease and is focused on safety.

Phase II Clinical Trials

In Phase II clinical trials, controlled studies are conducted on approximately 100 to 300 volunteer patients with the targeted disease. The preliminary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine if there are any side effects. These studies generally take approximately two years and cost between \$500,000 and \$4 million per trial, and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety.

Phase III Clinical Trials

This phase typically lasts about three years, usually involves 1,000 to 3,000 patients and cost between \$5 and \$50 million per trial. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any reactions that may result from long-term use of the drug.

11

New Drug Application

After the completion of all three clinical trial phases, if the data indicate that the drug is safe and effective, a New Drug Application, or NDA, is filed with the FDA. The NDA must contain all of the information on the drug gathered to that date, including data from the clinical trials. NDAs are often over 100,000 pages in length. The average NDA review time for new pharmaceuticals approved in 2000 was 15.6 months, up from 11.6 months in 1999.

Marketing Approval

If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional studies (Phase IV) to evaluate long-term effects.

Phase IV Clinical Trials and Post Marketing Studies

In addition to studies requested by the FDA after approval, these trials and studies are conducted to explore new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community.

Competition

Companies in the cancer vaccine development area include Progenics Pharmaceutical, Inc., Corixa Corporation, Biomira Inc. and Bristol Meyers-Squibb. Several companies are pursuing the development of antisense technology, including Eli Lilly, Merck, Genta Incorporated, and ISIS Pharmaceuticals. All of these companies have products in development stages, and, in some cases, are in human trials with antisense compounds generally similar to our NEUGENE compounds.

While we believe that none of these companies is likely to introduce an additional antisense compound into the broad commercial market in the immediate future, many pharmaceutical and biotechnology companies, including most of those listed above, have financial and technical resources greater than those currently available to us and have more established collaborative relationships with industry partners than we do. We believe that the combination of pharmaceutical properties of our NEUGENE compounds for restenosis, cancer, and drug metabolism affords us competitive advantages when compared with the antisense compounds of competitors.

We can also expect to compete with other companies exploiting alternative technologies that address the same therapeutic needs as do our technologies. The biopharmaceutical market is subject to rapid technological change, and it can be expected that competing technologies will emerge and will present a competitive challenge to us.

Research and Development

The Company expensed \$15,284,396, \$22,413,892 and \$12,750,901 on research and development activities during the years ended December 31, 2003, 2002 and 2001, respectively. Research and development (R&D) expenses included related salaries, contractor fees, materials, utilities and allocations of corporate costs. R&D expenses consisted of independent R&D costs and costs associated with collaborative development arrangements. In addition, the Company funded R&D at other companies and research institutions under agreements. Research and development costs are expensed as incurred.

12

Employees

As of December 31, 2003, we had 106 employees, 22 of whom hold advanced degrees. Ninety-seven employees are engaged directly in research and development activities, and nine are in administration. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

Where You Can Find Additional Information

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. For further information with respect to us, you may read and copy our reports, proxy statements and other information, at the SEC's public reference rooms at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, as well as at the SEC's regional offices at 500 West Madison Street, Suite 1400, Chicago, IL 60661 and at 233 Broadway, New York, NY 10279. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our SEC filings are also available at the SEC's web site at "<http://www.sec.gov>." In addition, you can read and copy our SEC filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street, N.W., Washington, D.C. 20006.

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as well as our corporate governance guidelines, outline of directorship qualifications, code of business conduct and the charter of our audit committee, compensation committee, and nominations committee are all available on our website (www.avibio.com) or by sending a request for a paper copy to: AVI BioPharma, Inc., One S.W. Columbia Ave., Suite 1105, Portland, Oregon 97258, attn. Investor Relations.

13

Item 2. Description of Property

We occupy 50,000 square feet of leased laboratory and office space at 4575 S.W. Research Way, Suite 200, Corvallis, Oregon 97333. The lease on our space expires in December 2007. Our executive office is located in 2,400 square feet of leased space at One S.W. Columbia, Suite 1105, Portland, Oregon 97258. This lease expires July 2004. We believe that our facilities are suitable and adequate for our present operational requirements for the foreseeable future.

Item 3. Legal Proceedings

As of March 15, 2004, there were no material, pending legal proceedings to which we are a party. From time to time, we become involved in ordinary, routine or regulatory legal proceedings incidental to our business.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of our shareholders during the quarter ended December 31, 2003.

14

Item 5. Market for Common Equity and Related Stockholder Matters

Our Common Stock is quoted on the Nasdaq National Market System (“Nasdaq NMS”) under the symbol “AVII.” The following table sets forth the high and low closing sales prices as reported by Nasdaq NMS for each quarterly period in the two most recent fiscal years and quarter-to-date for the next fiscal year:

	High	Low
2002		
Quarter 1	\$ 12.97	\$ 8.04
Quarter 2	7.95	2.70
Quarter 3	5.34	2.71
Quarter 4	6.39	4.60
2003		
Quarter 1	\$ 5.83	\$ 2.04
Quarter 2	7.05	3.31
Quarter 3	6.15	4.31
Quarter 4	5.50	4.00
2004		
Quarter 1 to March 12, 2004	\$ 4.75	\$ 3.07

The number of shareholders of record and approximate number of beneficial holders on March 4, 2004 was 618 and 15,600 respectively. There were no cash dividends declared or paid in fiscal years 2003 or 2002. We do not anticipate declaring such dividends in the foreseeable future.

All securities sold during 2003 by us were either previously reported on our Form 10-Qs filed with the Securities and Exchange Commission or sold pursuant to Registration statements filed under the Securities Act of 1933.

During 2003, we issued 30,467 shares of common stock to employees at approximately \$4.06 per share for \$123,576, under our Employee Stock Purchase Plan. During 2002, we issued 31,766 shares of common stock to employees at approximately \$4.74 per share for \$150,558, under our Employee Stock Purchase Plan.

During 2003, we granted 212,500 stock options to purchase shares of common stock at approximately \$5.07 per share, under our 2002 Equity Incentive Plan. During 2002, we granted 1,195,338 stock options to purchase shares of common stock at approximately \$4.99 per share, under our 2002 Equity Incentive Plan. The information required by Item 201(D) of Regulation S-K is incorporated by reference to Note 4 (“Shareholders’ Equity”) to Notes to Audited Financial Statements for the Year Ended December 31, 2003 page F-13

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with Item 7. “Management’s Discussion and Analysis or Plan of Operation” and Item 8. “Financial Statements.”

	YEAR ENDED DECEMBER 31,				
	2003	2002	2001	2000	1999
Operations data:					
Revenues	\$ 969,866	\$ 836,784	\$ 706,102	\$ 1,297,338	\$ 17,024
Research and development	15,284,396	22,413,892	12,750,901	9,268,330	6,672,027
General and administrative	4,558,948	3,763,941	3,357,817	2,270,302	1,745,491
Acquired in-process research and development	—	—	—	—	71,874
Realized gain on sale of short-term securities—available-for-sale	3,765,752	—	—	—	—
Write-down of short-term securities—available-for-sale	—	(4,478,260)	(12,523,088)	—	—
Net loss	(14,616,628)	(29,359,051)	(26,925,174)	(9,239,956)	(8,278,441)
Net loss per share — basic and diluted	(0.49)	(1.14)	(1.20)	(0.49)	(0.62)
Balance sheet data:					
Cash and investments	\$ 37,599,136	\$ 19,293,645	\$ 25,597,121	\$ 32,112,099	\$ 11,620,505
Working capital	34,639,526	15,279,854	24,230,010	31,408,473	10,611,593
Total assets	47,145,023	28,603,757	33,815,113	35,088,393	12,929,628
Shareholders’ equity	43,394,030	23,481,623	30,534,047	33,365,601	11,889,474

Item 7. Management’s Discussion and Analysis or Plan of Operations

Forward-Looking Information

This report contains forward-looking statements regarding our plans, expectations, estimates and beliefs. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “will,” “may,” and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. We have based these forward-looking statements largely on our expectations. Forward-looking statements in this report include, but are not necessarily limited to, those relating to:

- our intention to introduce new products,

- receipt of any required FDA or other regulatory approval for our products,
- our expectations about the markets for our products,
- acceptance of our products, when introduced, in the marketplace,
- our future capital needs, and
- success of our patent applications.

Forward-looking statements are subject to risks and uncertainties, certain of which are

16

beyond our control. Actual results could differ materially from those anticipated as a result of the factors described in the “Risk Factors” and detailed in our other Securities and Exchange Commission filings, including among others:

- the effect of regulation by the FDA and other governmental agencies,
- delays in obtaining, or our inability to obtain, approval by the FDA or other regulatory authorities for our products,
- research and development efforts, including delays in developing, or the failure to develop, our products,
- the development of competing or more effective products by other parties,
- the results of pre-clinical and clinical testing,
- uncertainty of market acceptance of our products,
- problems that we may face in manufacturing, marketing, and distributing our products,
- our inability to raise additional capital when needed,
- delays in the issuance of, or the failure to obtain, patents for certain of our products and technologies, and
- problems with important suppliers and business partners.

Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report or incorporated by reference might not transpire. Factors that cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the “Risk Factors” section and elsewhere in this report.

Overview

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. We have been unprofitable since inception and, other than limited interest and grant revenue, we have had no material revenues from the sale of products or from other sources, and we do not expect material revenues for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue to expand our research and development efforts and enter additional collaborative efforts. As of December 31, 2003, our accumulated deficit was \$131,194,686.

Results of Operations

Year Ended December 31, 2003 Compared with Year Ended December 31, 2002. Revenues, from license fees, grants and research contracts, increased from \$836,784 in 2002 to \$969,866 in 2003, primarily due to increases in research contracts revenues, partially offset by decreases in grants revenues. Operating expenses decreased from \$26,177,833 in 2002 to \$19,843,344 in 2003 due to decreases in research and development, primarily due to lower manufacturing costs associated with the Company’s clinical development efforts, which decreased from \$22,413,892 in 2002 to \$15,284,396 in 2003. Approximately \$7,000,000 of this decrease was due to the Company satisfying demand for certain NEUGENE components in 2003 by using quantities of the components which had

17

been manufactured and expensed in 2002. Additionally, general and administrative costs increased from \$3,763,941 in 2002 to \$4,558,948 in 2003 due to increases of \$610,000 in legal expenses and \$192,000 in director and officer insurance, consistent with industry trends. Net interest income increased from \$460,258 in 2002 to \$491,098 in 2003 due to earnings on increased cash balances, which were slightly offset by reductions in market interest rates. During the fourth quarter of 2003 the Company sold all of its investment in SuperGen, a related party, for a realized gain on sale of short-term securities—available-for-sale of \$3,765,752.

Year Ended December 31, 2002 Compared with Year Ended December 31, 2001. Revenues, from license fees, grants and research contracts, increased from \$706,102 in 2001 to \$836,784 in 2002, primarily due to increases in research contracts revenues, partially offset by decreases in grants revenues. Operating expenses increased from \$16,108,718 in 2001 to \$26,177,833 in 2002 due to increased expenses associated with outside collaborations and pre-clinical and clinical testing of the Company’s technologies which increased from \$12,750,901 in 2001 to \$22,413,892 in 2002. Approximately \$10,000,000 of this

increase was due to outside contractor GMP manufacturing costs of NEUGENES for Phase III clinical trials and potential commercial launch of the Resten-NG product. Additionally, general and administrative costs increased from \$3,357,817 in 2001 to \$3,763,941 in 2002 due to increases of \$220,000 in legal expenses, and \$219,000 for increased investor and public relations efforts. Net interest income decreased from \$1,000,530 in 2001 to \$460,258 in 2002 due to reductions in market interest rates on decreased cash balances from use in operations. In 2001 and 2002, the Company recorded non-cash write-downs of \$12,523,088 and \$4,478,260, respectively, on short-term securities—available-for-sale that had an other than temporary impairment in accordance with generally accepted accounting principles.

Liquidity and Capital Resources

We have financed our operations since inception primarily through equity sales totaling \$137,506,962, from grants and contract research funding of \$4,651,307 from various sources, and \$1,480,432 from shared development funding on AVICINE with SuperGen. We expect to continue to incur losses as we expand our research and development activities and related regulatory work and increase our collaborative efforts. For 2004, we expect our expenditures for operations, including our collaborative efforts, and our GMP facilities to be approximately \$23 to \$25 million. The increase from 2003 expenditures is expected from the purchase of additional NEUGENE components from an outside GMP manufacturer, coupled with additional clinical trial efforts. That cost could increase if we undertake additional collaborative efforts. However, if need be in 2004, we could reduce our expenditures because the vast majority of our costs are variable. Those estimated expenditures include amounts necessary to fulfill our obligations under our various collaborative, research and licensing agreements during 2004. Our expenditures for 2005 are expected to be greater than or equal to the 2004 estimate.

Because of the cost (up to \$500 million) and timeframe (up to 15 years) traditionally associated with developing a potential drug or pharmaceutical product to where FDA approval for human sales is received, our business strategy is to develop our products to initial Phase III human clinical trials and look for third parties to fund completion of development of the product and market the product through strategic partnerships, license agreements or other relationships, such as our research and development agreement and license agreement with Medtronic. We also look for collaborative and other efforts, such as our relationship with Exelixis, to utilize other technology to increase the potential variety and reduce the cost of identifying products. We currently use this strategy to limit the potential cost we would incur in developing a product. Our expected costs under our various contracts and for various drug development products can be estimated for the next year or two, but not

much beyond that due to the uncertainty of clinical trial results, research results and when we will find a partner to develop a potential drug.

Because of the various factors noted above and the expectation that, until we establish revenue sources, we will license to, or jointly develop our prospective products with, strategic partners, we review, at least annually, each research program and clinical trial, based on results and progress during the prior year and estimate our needs for that program or trial for the coming year, making adjustments based on the progress of the program during the year. We do not set long-term development budgets or development schedules for bringing our products to market or track our research costs on a product basis, other than against the current budgeted amount.

Our cash, cash equivalents and short-term securities were \$37,599,136 at December 31, 2003, compared with \$19,293,645 at December 31, 2002. The increase of \$18,305,491 was due primarily to the receipt of \$34,656,511 in net proceeds from two private equity financings and \$420,823 from the exercise of options and sales under the Company's employee stock purchase plan, offset by \$17,480,752 used in operations and \$2,037,084 used for purchases of property and equipment and patent related costs. The first of the two private equity financings with several institutional investors closed on May 6, 2003. The Company sold 4,546,211 shares of common stock at \$5.00 per share. Investors also received warrants for the purchase of 2,250,000 common shares in the aggregate for \$7.00 per share. These warrants are immediately exercisable and expire in May 2008. The second of the two private equity financings with several institutional investors closed on December 8, 2003. The Company sold 3,246,753 shares of common stock at \$4.62 per share. These investors received warrants for the purchase of 974,026 common shares in the aggregate for \$5.50 per share. These warrants are immediately exercisable and expire in December 2008. These investors also received warrants for the purchase of 1,623,377 common shares in the aggregate for \$4.62 per share. These warrants were exercised on January 22, 2004 with proceeds to the Company of \$7,500,000. Upon exercise of these warrants in January 2004, these investors received additional new five year warrants to purchase 389,611 shares of common stock in the aggregate at an exercise price of \$5.50 per share.

Our short-term securities represent investments in commercial paper. In 2002, short-term securities also included an investment in common stock of SuperGen, a related party, with a fair market value of \$1,625,608 at December 31, 2002. During the fourth quarter of 2003 the Company sold all of its investment in SuperGen. The Company reviews the fair market value of its short-term securities in relation to its cost basis of the securities on a quarterly basis. If a decline in fair market value below the cost basis is judged to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge.

We do not expect any material revenues in 2004 or 2005 from our business activities. We expect that our cash requirements for the balance of calendar 2004 will be satisfied by existing cash resources. To fund our operations beyond 2005, we will need to raise additional capital. We will continue to look for opportunities to finance our ongoing activities and operations through accessing corporate partners or the public equity markets, as we currently have no credit facility, nor do we intend to seek one.

In May 2001, the Company entered into a license and development agreement with Medtronic relating to the Company's antisense compounds which may have application in the treatment of vascular disease. The Company also entered into a separate stock purchase agreement with Medtronic International, Ltd. (then Medtronic Asset Management, Inc.) for \$10,000,000 in cash in exchange for 1,408,451 shares of AVI common stock and a warrant to purchase 3,000,000 shares of AVI common stock at \$10.00 per share. Closing of the transaction occurred during the second quarter of 2001.

CONTRACTUAL PAYMENT OBLIGATIONS

The Company's off-balance sheet arrangements are limited to operating leases and rents on certain facilities and equipment and license agreements for which it is obligated to pay the licensors a minimum annual royalty. These off-balance sheet arrangements are expensed as incurred. A summary of our contractual commitments and obligations as of December 31, 2003 is as follows:

Contractual Obligation	Payments Due By Period				
	Total	2004	2005 and 2006	2007 and 2008	2009 and beyond
Operating leases	\$ 3,519,000	\$ 882,000	\$ 1,758,000	\$ 879,000	\$ —
Royalty payments	2,380,000	125,000	250,000	250,000	1,755,000
	<u>\$ 5,899,000</u>	<u>\$ 1,007,000</u>	<u>\$ 2,008,000</u>	<u>\$ 1,129,000</u>	<u>\$ 1,755,000</u>

Our future expenditures and capital requirements depend on numerous factors, most of which are difficult to project beyond the short term, including without limitation, the progress of our research and development programs, the progress of our pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, our ability to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of our products. Our cash requirements are expected to continue to increase each year as we expand our activities and operations. There can be no assurance, however, that we will ever be able to generate product revenues or achieve or sustain profitability.

New Accounting Pronouncements

See Note 2 of Notes to Financial Statements included under Part III, Item 15.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to valuation of investments, long-lived assets, and revenue recognition. We base our estimates on historical experience and on various other assumptions. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies and the related judgments and estimates affect the preparation of our financial statements.

Valuation of Investments

Investments in marketable securities are recorded at fair value each period with changes recorded to other comprehensive income. We periodically evaluate our investments for other than temporary impairments and record an impairment unless the positive evidence indicating the carrying amount is recoverable outweighs the negative evidence to the contrary.

Revenue Recognition

Revenue is recorded from research contracts and grants as the services are performed and payment is reasonably assured. Upfront, nonrefundable fees and other fees associated with

license and development arrangements are recognized as revenue ratably over the performance period. Revenue associated with performance milestones under license and development arrangements is recognized based upon the achievement of the milestones, as defined in the respective agreements. Fees received from SuperGen pursuant to our Avicine shared development arrangement are netted against research and development expense since the Company and SuperGen share equally in all clinical development and FDA registration costs. Revenue from license and development arrangements has been insignificant to date.

Long-Lived Asset Impairment

We regularly evaluate long-lived assets and certain identified intangible assets for impairment in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," which requires us to review our long-lived assets and certain identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable and exceeds its fair value. Recoverability is assessed utilizing an un-discounted cash flow analysis and if less than the carrying value is compared to the fair value for assessing impairment. Based on this analysis, we did not recognize an impairment on long-lived assets during the year ended December 31, 2003. If circumstances related to our long-lived assets change, we may record an impairment charge in the future.

Risks Affecting Future Operating Results

We do not provide forecasts of our future financial performance. While we are optimistic about our long-term prospects, the following factors should be considered in evaluating our outlook. If the possibilities described as risks below actually occur, our operating results and financial condition would likely suffer and the trading price of our common stock may fall, causing a loss of some or all of an investment in our common stock.

Our products are in an early stage of development and may not be determined to be safe or effective.

We are only in the early stages of clinical development with our NEUGENE antisense pharmaceutical products. We have devoted almost all of our time to research and development of our technology and products, protecting our proprietary rights and establishing strategic alliances. Our proposed products are in the pre-clinical or clinical stages of development and will require significant further research, development, clinical testing and regulatory clearances. We have no products available for sale and we do not expect to have any products available for sale for several years. Our proposed products are subject to development risks. These risks include the possibilities that any of the products could be found to be ineffective or toxic, or could fail to receive necessary regulatory clearances. Although we have obtained favorable results in Phase II trials using AVICINE to treat colorectal and pancreatic cancer patients, we may not obtain similar or more favorable results in future clinical trials. We have not received any significant revenues from the sale of products and we may not successfully develop marketable products that will increase sales and, given adequate margins, make us profitable. Third parties may develop superior or equivalent, but less expensive, products.

We have incurred net losses since our inception, and we may not achieve or sustain profitability.

We incurred a net loss of \$29.4 million in 2002 and of \$14.6 million in 2003, including in 2002 a \$4.5 million non-cash write-down of investment securities in accordance with SEC accounting rules. In 2003 the Company sold all of its investment in SuperGen, Inc., a related party, for a realized gain on sale of

of December 31, 2003, our accumulated deficit was \$131.2 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from selling, general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our ability to raise additional capital, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

If we fail to attract significant additional capital, we may be unable to continue to successfully develop our products.

Since we began operations, we have obtained operating funds primarily by selling shares of our company. Based on our current plans, we believe that current cash balances will be sufficient to meet our operating needs for the current fiscal year. Furthermore, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. These factors include the success of our research and development efforts, the status of our pre-clinical and clinical testing, costs relating to securing regulatory approvals and the costs and timing of obtaining new patent rights, regulatory changes, competition and technological developments in the market. We may need funds sooner than currently anticipated.

If necessary, potential sources of additional funding could include strategic relationships, public or private sales of shares of our common stock or debt or other arrangements. We may not obtain additional funding when we need it on terms that will be acceptable to us or at all. If we raise funds by selling additional shares of our common stock or securities convertible into our common stock, the ownership interest of our existing shareholders will be diluted. If we are unable to obtain financing when needed, our business and future prospects would be materially adversely affected.

If we fail to receive necessary regulatory approvals, we will be unable to commercialize our products.

All of our products are subject to extensive regulation by the United States Food and Drug Administration, or FDA, and by comparable agencies in other countries. The FDA and comparable agencies require new pharmaceutical products to undergo lengthy and detailed clinical testing procedures and other costly and time-consuming compliance procedures. AVICINE has completed three Phase I and three Phase II studies. Our first NEUGENE antisense drug, Resten-NG, completed Phase I trials in late 2001 and a Phase II trial in 2002. We initiated two additional Phase Ib studies in 2001 for cancer and polycystic kidney disease and completed three Phase I trials on drug metabolism. Except for clinical trials underway or ready to start, we may not initiate additional trials when predicted or at all, or complete our clinical trials that are started or in a timely fashion. We do not know when or if we will be able to submit our products for regulatory review. Even if we submit a new drug application, there may be delays in obtaining regulatory approvals, if we obtain them at all. Sales of our products outside the United States will also be subject to regulatory requirements governing clinical trials and product approval. These requirements vary from country to country and could delay introduction of our products in those countries. We cannot assure you that any of our products will receive marketing approval from the FDA or comparable foreign agencies.

We may fail to compete effectively, particularly against larger, more established pharmaceutical companies, causing our business to suffer.

The biotechnology industry is highly competitive. We compete with companies in the United

States and abroad that are engaged in the development of pharmaceutical technologies and products. They include: biotechnology, pharmaceutical, chemical and other companies; academic and scientific institutions; governmental agencies; and public and private research organizations.

Many of these companies and many of our other competitors have much greater financial and technical resources and production and marketing capabilities than we do. Our industry is characterized by extensive research and development and rapid technological progress. Competitors may successfully develop and market superior or less expensive products which render our products less valuable or unmarketable.

We have limited operating experience.

We have engaged solely in the development of pharmaceutical technology. Although some members of our management team have experience in biotechnology company operations, we have limited experience in manufacturing or selling pharmaceutical products. We also have only limited experience in negotiating and maintaining strategic relationships, and in conducting clinical trials and other later-stage phases of the regulatory approval process. We may not successfully engage in some or all of these activities.

We have limited manufacturing capability.

While we believe that we can produce materials for clinical trials and produce products for human use at our recently completed GMP manufacturing facility, we may need to, expand our commercial manufacturing capabilities for products in the future if we elect not to or cannot contract with others to manufacture our products. This expansion may occur in stages, each of which would require regulatory approval, and product demand could at times exceed supply capacity. We have not selected a site for any expanded facilities and do not know what the construction cost will be for such facilities and whether we will have the financing needed for such construction. We do not know if or when the FDA will determine that such facilities comply with Good Manufacturing Practices. The projected location and construction of any facilities will depend on regulatory approvals, product development, pharmaceutical partners and capital resources, among other factors. We have not obtained regulatory approvals for any production facilities for our products, nor can we assure investors that we will be able to do so.

If we lose key personnel or are unable to attract and retain additional, highly skilled personnel required for our activities, our business will suffer.

Our success will depend to a large extent on the abilities and continued service of several key employees, including Drs. Denis Burger, Patrick Iversen, and Dwight Weller. We maintain key man life insurance in the amount of \$1,000,000 for Dr. Burger and \$500,000 for each of Drs. Iversen and Weller. The loss of any of these key employees could significantly delay the achievement of our goals. Competition for qualified personnel in our industry is intense, and our

success will depend on our ability to attract and retain highly skilled personnel. To date, we have been successful in attracting and retaining key personnel. We are not aware of any key personnel who plan to retire or otherwise leave the Company in the near future.

Asserting, defending and maintaining our intellectual property rights could be difficult and costly, and our failure to do so will harm our ability to compete and the results of our operations.

Our success will depend on our existing patents and licenses, and our ability to obtain

additional patents in the future. A patent estate including 138 patents (domestic and foreign) issued or licensed to us, and 130 pending patent applications (domestic and foreign) protects our technologies. We license the composition, manufacturing and use of AVICINE in all fields, except fertility regulation from The Ohio State University, and we license other patents for certain complementary technologies from others.

Some of our patents on core technologies expire as early as 2008, including for NEUGENES; however, based on patented improvements and additions to such core patents, we believe our patent protection for those products and other products would extend beyond 2020.

We cannot assure investors that our pending patent applications will result in patents being issued in the United States or foreign countries. In addition, the patents which have been or will be issued may not afford meaningful protection for our technology and products. Competitors may develop products similar to ours which do not conflict with our patents. Others may challenge our patents and, as a result, our patents could be narrowed or invalidated. The patent position of biotechnology firms generally is highly uncertain, involves complex legal and factual questions, and has recently been the subject of much litigation. No consistent policy has emerged from the United States Patent and Trademark Office (USPTO), or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents. In addition, there is a substantial backlog of biotechnology patent applications at the USPTO and the approval or rejection of patents may take several years.

Our success will also depend partly on our ability to operate without infringing upon the proprietary rights of others, as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. We have not received any communications or other indications from owners of related patents or others that such persons believe our products or technology may infringe their patents. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. Any required license may not be available to us on acceptable terms, or at all. If we fail to obtain a license, our business might be materially adversely affected.

To help protect our proprietary rights in unpatented trade secrets, we require our employees, consultants and advisors to execute confidentiality agreements. However, such agreements may not provide us with adequate protection if confidential information is used or disclosed improperly. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Further, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets.

If our strategic relationships are unsuccessful, our business could be harmed.

Our strategic relationships with SuperGen, Medtronic, Exelixis and others are important to our success. The development, improvement and marketing of many of our key therapeutic products are or will be dependent on the efforts of our strategic partners. For example, under the SuperGen relationship, we may fail to achieve clinical and sales milestones; AVICINE may fail to achieve regulatory approval; AVICINE may not be commercially successful; SuperGen may fail to perform its obligations under our agreements, such as failing to devote sufficient resources to marketing AVICINE; and our agreements with SuperGen may be terminated against our will. Similarly, under the Medtronic relationship, we are currently dependent on Medtronic to achieve clinical and other milestones, to obtain regulatory approval and to

commercially exploit our antisense compounds, including Resten-NG, in certain treatments of vascular disease; which products may not be developed or, if developed may not be commercially successful; if Medtronic fails to perform its obligations under our agreements, such as failing to devote sufficient resources to development or to market such products. We may also need additional future funding, including for operations, product development and our other activities. We may receive additional funding from our strategic partners, including SuperGen and Medtronic, under existing agreements. We may not receive any additional payments from SuperGen or Medtronic and those relationships may not be commercially successful. The transactions contemplated by our agreements with strategic partners, including the equity purchases and cash payments, are subject to numerous risks and conditions. The occurrence of any of these events could severely harm our business.

Our near-term strategy is to co-develop products with strategic partners or to license the marketing rights for our products to pharmaceutical partners after we complete one or more Phase II clinical trials. In this manner, the extensive costs associated with late-stage clinical development and marketing will be shared with, or the responsibility of, our strategic partners.

To fully realize the potential of our products, including development, production and marketing, we may need to establish other strategic relationships.

We have limited sales capability and may not be able to successfully commercialize our products.

We have been engaged solely in the development of pharmaceutical technology. Although some of our management have experience in biotechnology company operations, we have limited experience in manufacturing or selling pharmaceutical products. We also have only limited experience in negotiating and maintaining strategic relationships, and in conducting clinical trials and other later-stage phases of the regulatory approval process. To the extent we rely on strategic partners to fully commercialize our products, we will be dependent on their efforts. We may not successfully engage in any of these activities.

We may be subject to product liability lawsuits and our insurance may not be adequate to cover damages.

We believe we carry adequate insurance for the product development research we currently conduct. In the future, when we have products available for commercial sale and use, the use of our products will expose us to the risk of product liability claims. Although we intend to obtain product liability insurance coverage, product liability insurance may not continue to be available to us on acceptable terms and our coverage may not be sufficient to cover all claims against us. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses, lowering our earnings and, depending on revenues, potentially resulting in additional losses.

Continuing efforts of government and third party payers to contain or reduce the costs of health care may adversely affect our revenues and future profitability.

In addition to obtaining regulatory approval, the successful commercialization of our products will depend on our ability to obtain reimbursement for the cost of the product and treatment. Government authorities, private health insurers and other organizations, such as health maintenance organizations are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the growth of healthcare organizations such as HMOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of

healthcare services and products, resulting in lower prices and reducing demand for our products. The cost containment measures that healthcare providers are instituting and any healthcare reform could affect our ability to sell our products and may have a material adverse effect on our operations. Reimbursement in the United States or foreign countries may not be available for any of our products, any reimbursement granted may be reduced or discontinued, and limits on reimbursement available from third-party payors may reduce the demand for, or the price of, our products. The lack or inadequacy of third-party reimbursements for our products would have a material adverse effect on our operations. Additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future that adversely affects our products and our business.

If we fail to establish strategic relationships with larger pharmaceutical partners, our business may suffer.

We do not intend to conduct late-stage (Phase III) human clinical trials ourselves. We anticipate entering into relationships with larger pharmaceutical companies to conduct later pharmaceutical trials and to market our products and we also plan to continue to use contract manufacturing for late stage clinical and commercial quantities of our products. We may be unable to enter into corporate partnerships which could impede our ability to bring our products to market. Any such corporate partnerships, if entered, may not be on favorable terms and may not result in the successful development or marketing of our products. If we are unsuccessful in establishing advantageous clinical testing, manufacturing and marketing relationships, we are not likely to generate significant revenues and become profitable.

We use hazardous substances in our research activities

We use organic and inorganic solvents and reagents in our clinical development that are customarily used in pharmaceutical development and synthesis. Some of those solvents and reagents we use, such as methylene chloride, isopropyl alcohol, ethyl acetate and acetone, may be classified as hazardous substances, are flammable and, if exposed to human skin can cause anything from irritation to severe burns. We receive, store, use and dispose of such chemicals in compliance with all applicable laws with containment storage facilities and contained handling and disposal safeguards and procedures. We are routinely inspected by federal, state and local governmental and public safety agencies regarding our storage, use and disposal of such chemicals, including the federal Occupational Safety and Health Agency (“OSHA”), the Oregon Department of Environmental Quality (“DEQ”) and local fire departments, without any material noncompliance issues in such inspections. Further, our usage of such chemicals is limited and falls below the reporting thresholds under federal law. Based on our limited use of such chemicals, the nature of such chemicals and the safeguards undertaken by the Company for storage, use and disposal, we believe we do not have any material exposure for toxic tort liability. Further, the cost of such compliance is not a material cost in our operating budget. While we do not have toxic tort liability insurance at this time, we believe our current insurance coverage is adequate to cover most liabilities that may arise from our use of such substances. If we are wrong in any of our beliefs, we could incur a liability in certain circumstances that would be material to our finances and the value of an investment in our securities.

Risks Related to Share Ownership

Our right to issue preferred stock, our classified Board of Directors and Oregon Anti-Takeover laws may delay a takeover attempt and prevent or frustrate any attempt to replace or remove the then current management of the Company by shareholders.

Our authorized capital consists of 200,000,000 shares of common stock and 20,000,000

shares of preferred stock. Our board of directors, without any further vote by the shareholders, has the authority to issue preferred shares and to determine the price, preferences, rights and restrictions, including voting and dividend rights, of these shares. The rights of the holders of shares of common stock may be affected by the rights of holders of any preferred shares that our board of directors may issue in the future. For example, our board of directors may allow the issuance of preferred shares with more voting rights, higher dividend payments or more favorable rights upon dissolution, than the shares of common stock or special rights to elect directors.

In addition, we have a “classified” board of directors, which means that only one-half of our directors are eligible for election each year. Therefore, if shareholders wish to change the composition of our Board of Directors, it could take at least two years to remove a majority of the existing directors or to change all directors. Having a classified board of directors may, in some cases, delay mergers, tender offers or other possible transactions which may be favored by some or a majority of our shareholders and may delay or frustrate action by shareholders to change the then current Board of Directors and management.

The Oregon Control Share Act and Business Combination Act may limit parties who acquire a significant amount of voting shares from exercising control over us for specific periods of time. These acts may lengthen the period for a proxy contest or for a person to vote their shares to elect the majority of our

Our stock price is volatile and may fluctuate due to factors beyond our control.

Historically, the market price of our stock has been highly volatile as reflected in the table in Part II, Item 5 of this report. The following types of announcements could have a significant impact on the price of our common stock: positive or negative results of testing and clinical trials by ourselves or competitors; delays in entering into corporate partnerships; technological innovations or commercial product introductions by ourselves or competitors; changes in government regulations; developments concerning proprietary rights, including patents and litigation matters; public concern relating to the commercial value or safety of any of our products; or general stock market conditions.

Further, the stock market experiences significant price and volume fluctuations. These fluctuations have particularly affected the market prices of equity securities of many biopharmaceutical companies that are not yet profitable. Often, the effect on the price of such securities is unrelated or disproportionate to the operating performance of such companies. These broad market fluctuations may adversely affect the ability of a shareholder to dispose of his or her shares at a price equal to or above the price at which the shares were purchased.

The significant number of our shares of Common Stock eligible for future sale may cause the price of our common stock to fall.

We have outstanding 34,465,737 shares of common stock as of December 31, 2003 and all are eligible for sale under Rule 144 or are otherwise freely tradeable. In addition:

- Our employees and others hold options to buy a total of 3,333,861 shares of common stock of which 2,556,828 shares were exercisable at December 31, 2003. The options outstanding have exercise prices between \$.04 to \$10 per share. The shares of common stock to be issued upon exercise of these options, have been registered, and therefore may be freely sold when issued;
- There are outstanding warrants to buy 11,662,382 shares of common stock at December 31, 2003 with exercise prices ranging from \$.0003 to \$35.63 per share. All of these

shares of common stock are registered for resale and may be freely sold when issued.

- We may issue options to purchase up to an additional 1,889,063 shares of common stock at December 31, 2003 under our stock option plans, which also will be fully saleable when issued.
- We are authorized to sell up to 150,579 shares of common stock under our Employee Stock Purchase Plan to our full-time employees, nearly all of whom are eligible to participate.
- We have also granted certain contractual rights to purchase (i) an additional 352,113 shares of our common stock at a price of \$7.10 per share and (ii) the right to purchase up to \$7,500,000 of our common stock based on the average closing sales price for the five days preceding the commitment to purchase. If we meet certain technological milestones, the holder of these rights is obligated to purchase shares of common stock from us. The holder of these rights may require us to register the shares issued upon the exercise of such purchase rights.

Sales of substantial amounts of shares into the public market could lower the market price of our common stock.

We do not expect to pay dividends in the foreseeable future.

We have never paid dividends on our shares of common stock and do not intend to pay dividends in the foreseeable future. Therefore, you should only invest in our common stock with the expectation of realizing a return through capital appreciation on your investment. You should not invest in our common stock if you are seeking dividend income.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Due to the short-term nature of our interest bearing assets we believe that our exposure to interest rate market risk is not significant.

Item 8. Financial Statements

All information required by this item begins on page F-1 in item 15 of Part III of this Report and is incorporated into this item by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

On May 15, 2002, AVI BioPharma, Inc. ("AVI") dismissed Arthur Andersen LLP as its independent public accountants. On May 21, 2002, AVI engaged KPMG LLP ("KPMG") as its new independent public accountants. AVI's Board of Directors ("Board") approved the dismissal. All members of the Board's Audit Committee, except one, participated in the decision to dismiss Arthur Anderson at AVI's May 15, 2002 Board meeting. The engagement of KPMG was approved by AVI's Board. The absent Audit Committee member was notified of the change following the meeting and ratified the change. AVI shareholders ratified the change at the May 14, 2003 AVI shareholder meeting.

None of Arthur Andersen's reports on AVI's consolidated financial statements for the fiscal years ended December 31, 2000 and 2001 contained an adverse opinion or disclaimer of opinion, nor was any such report qualified or modified as to uncertainty, audit scope or accounting principles. The Company filed a current report on Form 8-K with the SEC on May 22, 2002, as amended by filings with the SEC on May 31, 2002 and June 10, 2002 (collectively, the "Form 8-K").

During the fiscal years ended December 31, 2000 and 2001 and through May 15, 2002, there were no disagreements between AVI and Arthur Andersen on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to Arthur Andersen's satisfaction, would have caused them to make reference to the subject matter of the disagreements in connection with their reports on AVI's consolidated financial statements for such years or such period, and there were no reportable events as set forth in Item 304(a)(1)(v) of Regulation S-K.

During the fiscal years ended December 31, 2000 and 2001 and through May 21, 2002, AVI did not consult KPMG regarding the application of accounting principles to any specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the AVI's financial statements, or any other matters or reportable events as set forth in Items 304(a)(2)(i) and (ii) of Regulation S-K.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Within the 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-14 and 15d-14 under the Securities Exchange Act of 1934. Based on their review of our disclosure controls and procedures, the President and Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to us that is required to be included in our periodic SEC filings.

29

Internal Controls and Procedures

There were no significant changes in internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

30

PART III

Item 10. Directors and Executive Officers of the Registrant

Information regarding our directors and executive officers required by this item is included in our definitive proxy statement for our 2004 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item is included in our definitive proxy statement for our 2004 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this item is included in our definitive proxy statement for our 2004 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

The information required by this item is included in our definitive proxy statement for our 2004 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item is included in our definitive proxy statement for our 2004 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

31

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

- (a) The following documents are filed as part of this Report:

Financial Statements

The following financial statements of the Company and the Report of KPMG LLP, Independent Auditors, are included in Part IV of this Report on the pages indicated:

[Report of KPMG LLP, Independent Auditors](#)

[Report of Arthur Andersen, Independent Auditors](#)

[Balance Sheets](#)

[Statements of Operations](#)

[Statements of Shareholders' Equity](#)

[Statements of Cash Flows](#)

Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

Exhibits

The following exhibits are filed herewith and this list is intended to constitute the exhibit index:

Exhibit No.	Description
3.1	Third Restated Articles of Incorporation of AntiVirals Inc. (1)
3.2	Bylaws of AntiVirals Inc. (1)
3.3	First Amendment to Third Restated Articles of Incorporation (4)
3.4	Amendment to Article 2 of the Company's Third Restated Articles of Incorporation (11)
4.1	Form of Specimen Certificate for Common Stock. (1)
4.2	Form of Warrant for Purchase of Common Stock. (1)
4.3	Form of Warrant Agreement. (1)
4.4	Form of Representative's Warrant. (1)
4.5	Form of Warrant Agreement between AntiVirals Inc. and ImmunoTherapy Shareholders (3)
4.6	Form of Common Stock Purchase Warrant. (5)
10.1	1992 Stock Incentive Plan (as amended through May 11, 2000). (1)
10.2	Employment Agreement with Denis R. Burger, Ph.D. dated November 4, 1996. (1)
10.3	Employment Agreement with Alan P. Timmins dated November 4, 1996. (1)
10.4	Employment Agreement with Dwight Weller, Ph.D. dated November 4, 1996. (1)
10.5	Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1992. (1)
10.6	Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc. dated January 20, 1996. (1)
10.7	License and Option Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1993. (1)
10.8	Commercial Lease between Research Way Investments, Landlord, and AntiVirals Inc., Tenant, dated June 15, 1992. (1)
10.9	Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated June 17, 1992.(1)
10.10	First Amendment to Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated July 24, 1995. (1)
10.11	Employment Agreement with Patrick L. Iversen, Ph.D. dated July 14, 1997. (2)
10.12	ImmunoTherapy Corporation 1997 Stock Option Plan (3)
10.13	License Agreement between ImmunoTherapy Corporation and Ohio State University, dated March 12, 1996 (3)
10.14	License Agreement between ImmunoTherapy Corporation and Ohio State University, dated December 26, 1996 (3)
10.15	Amendment to License Agreement between ImmunoTherapy Corporation and Ohio State University, dated September 23, 1997 (3)
10.16	Agreement and Plan of Reorganization and Merger dated as of February 2, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)
10.17	First Amendment to Plan of Reorganization and Merger dated as of May 27, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)

10.18	Second Amendment to Plan of Reorganization and Merger dated as of August 4, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)
10.19	Form of Escrow Agreement among AntiVirals Inc., the Escrow Indemnitors and Jeffrey Lillard (3)
10.20	Purchase Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.21	Registration Rights Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.22	Purchase Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.23	Registration Rights Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.24	Subscription Agreement, dated December 1, 1999, by and between SuperGen, Inc. and AVI BioPharma, Inc. (5)
10.25	2000 Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AVI BioPharma, Inc. (6)
10.26	United States of America Sales, Distribution, and Development Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.27	Common Stock and Warrant Purchase Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.28	Registration Rights Agreement, dated April 14, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.29	2000 Employee Share Purchase Plan (8)
10.30	Employment Agreement with Mark M. Webber dated May 11, 2000. (9)
10.31	Employment Agreement with David H. Mason, Jr. dated November 1, 2000. (9)
10.32	Lease Agreement with Spieker Partners, LP dated May 8, 2001. (9)
10.33*	Investment Agreement dated May 22, 2001 between the Company and Medtronic Asset Management, Inc. (9)
10.34	Warrant dated June 20, 2001 issued to Medtronic Asset Management, Inc. (9)
10.35	Registration Rights Agreement dated June 20, 2001 between the Company and Medtronic Asset Management, Inc. (9)
10.36*	License and Development Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)
10.37*	Supply Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)
10.38	Securities Purchase Agreement dated March 25, 2002 between the Company and certain purchasers ("SPA") (10)
10.39	Form of Warrant issued by the Company to certain purchasers under the SPA (10)
10.40	Registration Rights Agreement dated March 25, 2002 between the Company and certain purchasers (10)
10.41	2002 Equity Incentive Plan (11)
14.0	Code of Business Conduct and Ethics
23.0	Consent of KPMG LLP

31.1	Certification of the Company's Chief Executive Officer, Denis R. Burger, Ph.D., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Company's Chief Financial Officer, Mark M. Webber, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.0	Certification of CEO and CFO Pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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- (1) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form SB-2, as amended and filed with the Securities and Exchange Commission on May 29, 1997 (Commission Registration No. 333-20513).
 - (2) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, and filed with the Securities and Exchange Commission on March 30, 1998.
 - (3) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-4, as amended, and filed with the Securities and Exchange Commission on August 7, 1998 (Commission Registration No. 333-60849).
 - (4) Incorporated by reference to Exhibits to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on September 30, 1998 (Commission Registration No. 000-22613).
 - (5) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-3, as amended, and filed with the Securities and Exchange Commission on December 21, 1999 (Commission Registration No. 333-93135).
 - (6) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-1 and filed with the Securities and Exchange Commission on June 16, 2000 (Commission Registration No. 333-39542).
 - (7) Incorporated by reference to Exhibits to Registrant's Registrations Statement on Form S-3, and filed with the Securities and Exchange Commission on September 15, 2000 (Commission Registration No. 333-45888).
 - (8) Incorporated by reference to Appendix A to Registrant's Definitive Proxy Statement on Form 14-A, as amended, filed with the Securities and Exchange Commission on April 12, 2000.
 - (9) Incorporated by reference to Exhibits to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001, and filed with the Securities and Exchange Commission on August 14, 2001, as amended on April 23, 2002.
 - (10) Incorporated by reference to Exhibits to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on April 2, 2002.
 - (11) Incorporated by reference to appendixes to Registrant's Definitive Proxy Statement on Schedule 14-A, as filed with the Securities and Exchange Commission on April 11, 2002.

(b) Reports on Form 8-K. The following reports on Form 8-K were filed during the calendar quarter ended December 31, 2003.

Form 8-K, Items 5 and 7, October 29, 2003
Form 8-K, Items 5 and 7, October 29, 2003
Form 8-K, Items 5, 7 and 12, November 4, 2003
Form 8-K, Items 5, 7 and 12, November 5, 2003
Form 8-K, Items 5, 7 and 12, November 6, 2003
Form 8-K, Items 5, 7 and 12, November 11, 2003
Form 8-K, Items 5, 7 and 12, November 13, 2003
Form 8-K, Items 5, 7 and 12, November 14, 2003
Form 8-K, Items 5, 7 and 12, November 17, 2003
Form 8-K, Items 5 and 7, December 4, 2003
Form 8-K, Items 5, 7 and 12, December 10, 2003
Form 8-K, Items 5, 7 and 12, December 23, 2003
Form 8-K, Items 5, 7 and 12, December 30, 2003

(c) Exhibits. See Item 15 (a) above.

(d) Financial Statement Schedules. See Item 15 (a) above.

* A Confidential Treatment Request for certain information in this document has been filed with the Securities and Exchange Commission. The information for which treatment has been

sought has been deleted from such exhibit and the deleted text replaced by an asterisk (*).

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 15, 2004

AVI BIOPHARMA, INC.

By: /s/ Denis R. Burger, Ph.D.
Denis R. Burger, Ph.D.
Chairman of the Board and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in their capacities indicated on March 15, 2004:

<u>Signature</u>	<u>Title</u>
<u>/s/ DENIS R. BURGER, Ph.D.</u> Denis R. Burger, Ph.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
<u>/s/ ALAN P. TIMMINS</u> Alan P. Timmins	President, Chief Operating Officer, and Director
<u>/s/ MARK M. WEBBER</u> Mark M. Webber	Chief Financial Officer and Chief Information Officer (Principal Financial and Accounting Officer)
<u>/s/ PATRICK L. IVERSEN, Ph.D.</u> Patrick L. Iversen, Ph.D.	Senior Vice President of Research and Development and Director
<u>/s/ DWIGHT D. WELLER, Ph.D.</u> Dwight D. Weller, Ph.D.	Senior Vice President of Chemistry and Manufacturing and Director
<u>/s/ JOHN W. FARA, Ph.D.</u> John W. Fara, Ph.D.	Director
<u>/s/ ANDREW J. FERRARA</u> Andrew J. Ferrara	Director
<u>/s/ JAMES B. HICKS, Ph.D.</u> James B. Hicks, Ph.D.	Director
<u>/s/ JOSEPH RUBINFELD, Ph.D.</u> Joseph Rubinfeld, Ph.D.	Director

Independent Auditors' Report

To the Board of Directors and Shareholders of
AVI BIOPHARMA, INC.

We have audited the accompanying balance sheets of AVI BIOPHARMA, INC. (an Oregon corporation in the development stage) as of December 31, 2003 and 2002, and the related statements of operations, shareholders' equity and cash flows for each of the years in the two-year period ended December 31, 2003 and for the period from July 22, 1980 (inception) through December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of AVI BioPharma, Inc. for the year ended December 31, 2001 and for the period from July 22, 1980 (inception) through December 31, 2001, were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated February 21, 2002. Our opinion on the statements of operations, stockholders' equity and cash flows, insofar as it relates to the amounts included for the period from July 22, 1980 (inception) through December 31, 2001, is based solely on the report of the other auditors.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of AVI BIOPHARMA, INC. as of December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2003 and for the period from July 22, 1980 (inception) through December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

THIS REPORT IS A CONFORMED COPY OF THE REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP AND HAS NOT BEEN REISSUED BY THAT FIRM.

Report of Independent Public Accountants

To the Board of Directors and Shareholders of
AVI BIOPHARMA, INC.

We have audited the accompanying balance sheet of AVI BIOPHARMA, INC. (an Oregon corporation in the development stage) as of December 31, 2001, and the related statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2001 and for the period from inception (July 22, 1980) to December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of AVI BIOPHARMA, INC. as of December 31, 2001, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2001 and for the period from inception (July 22, 1980) to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Portland, Oregon
February 21, 2002

AVI BIOPHARMA, INC.
(A Development Stage Company)
BALANCE SHEETS

	December 31,	
	2003	2002
Assets		
Current Assets:		
Cash and cash equivalents	\$ 12,524,915	\$ 10,384,963
Short-term securities—available-for-sale	25,074,221	8,908,682
Related party receivables	—	513,250
Other current assets	791,383	595,093
Total Current Assets	<u>38,390,519</u>	<u>20,401,988</u>
Property and Equipment, net of accumulated depreciation and amortization of \$5,198,912 and \$4,007,186	7,008,426	6,584,290
Patent Costs, net of accumulated amortization of \$877,038 and \$727,901	1,716,231	1,587,632
Other Assets	29,847	29,847
Total Assets	<u>\$ 47,145,023</u>	<u>\$ 28,603,757</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 3,052,932	\$ 4,540,745
Accrued employee compensation	698,061	581,389
Total Current Liabilities	<u>3,750,993</u>	<u>5,122,134</u>
Commitments and Contingencies		
Shareholders' Equity:		
Preferred stock, \$.0001 par value, 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$.0001 par value, 200,000,000 shares authorized; 34,465,737 and 26,562,666 issued and outstanding	3,447	2,656
Additional paid-in capital	174,875,072	139,327,069
Accumulated other comprehensive income (loss)	(289,803)	729,956
Deficit accumulated during the development stage	(131,194,686)	(116,578,058)
Total Shareholders' Equity	<u>43,394,030</u>	<u>23,481,623</u>
Total Liabilities and Shareholders' Equity	<u>\$ 47,145,023</u>	<u>\$ 28,603,757</u>

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF OPERATIONS

	Year ended December 31,			July 22, 1980 (Inception) through December 31, 2003
	2003	2002	2001	
Revenues, from license fees, grants and research contracts	\$ 969,866	\$ 836,784	\$ 706,102	\$ 4,651,307
Operating expenses:				
Research and development	15,284,396	22,413,892	12,750,901	84,445,152
General and administrative	4,558,948	3,763,941	3,357,817	23,149,676
Acquired in-process research and development	—	—	—	19,545,028
	<u>19,843,344</u>	<u>26,177,833</u>	<u>16,108,718</u>	<u>127,139,856</u>
Other income (loss):				
Interest income, net	491,098	460,258	1,000,530	4,432,709
Realized gain on sale of short-term securities— available-for-sale	3,765,752	—	—	3,862,502
Write-down of short-term securities— available-for- sale	—	(4,478,260)	(12,523,088)	(17,001,348)
	<u>4,256,850</u>	<u>(4,018,002)</u>	<u>(11,522,558)</u>	<u>(8,706,137)</u>
Net loss	<u>\$ (14,616,628)</u>	<u>\$ (29,359,051)</u>	<u>\$ (26,925,174)</u>	<u>\$ (131,194,686)</u>
Net loss per share - basic and diluted	<u>\$ (0.49)</u>	<u>\$ (1.14)</u>	<u>(1.20)</u>	
Weighted average number of common shares outstanding for computing basic and diluted loss per share	<u>29,808,539</u>	<u>25,691,549</u>	<u>22,399,001</u>	

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF SHAREHOLDERS' EQUITY

	Partnership Units	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
		Shares	Amount				
BALANCE AT JULY 22, 1980 (Inception)	—	—	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of partnership units, warrants and common stock	3,615	8,272,916	828	33,732,654	—	—	33,733,482
Compensation expense related to issuance of warrants for common stock and partnership units	—	—	—	537,353	—	—	537,353
Exercise of warrants for partnership units and common stock	42	1,427,712	142	1,305,409	—	—	1,305,551
Exercise of options for common stock	—	488,957	49	2,203,312	—	—	2,203,361
Issuance of common stock for ESPP	—	7,769	1	42,371	—	—	42,372
Issuance of common stock and warrants for cash and securities, net of offering costs	—	7,582,267	758	50,660,536	—	—	50,661,294
Issuance of common stock and warrants for the acquisition of ImmunoTherapy Corporation	—	2,132,592	213	17,167,199	—	—	17,167,412
Issuance of common stock for consulting services, \$4.00 per share	—	17,400	2	69,598	—	—	69,600
Conversion of debt into common stock and partnership units	9	9,634	1	87,859	—	—	87,860
Issuance of common stock in exchange for partnership units	(1,810)	1,632,950	163	(163)	—	—	—
Withdrawal of partnership net assets upon conveyance of technology	(1,856)	—	—	(176,642)	—	—	(176,642)
Common stock subject to rescission, net	—	(64,049)	(6)	(288,789)	—	—	(288,795)
Comprehensive income (loss):	—	—	—	—	(11,683,414)	—	(11,683,414)
Unrealized loss on short-term securities— available-for-sale	—	—	—	—	—	(60,293,833)	(60,293,833)
Net loss	—	—	—	—	—	—	(71,977,247)
BALANCE AT DECEMBER 31, 2000	—	21,508,148	2,151	105,340,697	(11,683,414)	(60,293,833)	33,365,601
Exercise of warrants for common stock	—	86,027	8	344,998	—	—	345,006
Exercise of options for common stock	—	79,649	8	305,512	—	—	305,520
Issuance of common stock for ESPP	—	29,419	3	164,985	—	—	164,988
Issuance of common stock and warrants for services	—	37,197	4	359,996	—	—	360,000
Issuance of common stock and warrants for cash, net of offering costs	—	1,482,118	148	10,195,588	—	—	10,195,736
Comprehensive income (loss):	—	—	—	—	12,523,088	—	12,523,088
Write-down of short-term securities— available-for-sale	—	—	—	—	199,282	—	199,282
Unrealized gain on short-term securities— available-for-sale	—	—	—	—	—	(26,925,174)	(26,925,174)
Net loss	—	—	—	—	—	—	(14,202,804)
BALANCE AT DECEMBER 31, 2001	—	23,222,558	2,322	116,711,776	1,038,956	(87,219,007)	30,534,047
Exercise of warrants for common stock	—	17,119	2	158,758	—	—	158,760
Exercise of options for common stock	—	82,301	8	347,324	—	—	347,332
Issuance of common stock for ESPP	—	31,766	3	150,555	—	—	150,558
Issuance of common stock and warrants for services	—	138,251	14	489,649	—	—	489,663
Compensation expense related to issuance of options for common stock	—	—	—	148,254	—	—	148,254
Issuance of common stock and warrants for cash, net of offering costs	—	3,070,671	307	21,320,753	—	—	21,321,060
Comprehensive income (loss):	—	—	—	—	4,478,260	—	4,478,260
Write-down of short-term securities— available-for-sale	—	—	—	—	(4,787,260)	—	(4,787,260)
Unrealized loss on short-term securities— available-for-sale	—	—	—	—	—	(29,359,051)	(29,359,051)
Net loss	—	—	—	—	—	—	(29,668,051)
BALANCE AT DECEMBER 31, 2002	—	26,562,666	2,656	139,327,069	729,956	(116,578,058)	23,481,623
Exercise of options for common stock	—	79,640	8	297,239	—	—	297,247

Issuance of common stock for ESPP	—	30,467	3	123,573	—	—	123,576
Compensation expense related to issuance of options for common stock	—	—	—	471,460	—	—	471,460
Issuance of common stock and warrants for cash, net of offering costs	—	7,792,964	780	34,655,731	—	—	34,656,511
Comprehensive income (loss):							
Realized gain on sale of short-term securities— available-for-sale	—	—	—	—	(3,765,752)	—	(3,765,752)
Unrealized gain on short-term securities— available-for-sale, net	—	—	—	—	2,745,993	—	2,745,993
Net loss	—	—	—	—	—	(14,616,628)	(14,616,628)
Comprehensive loss	—	—	—	—	—	—	(15,636,387)
BALANCE AT DECEMBER 31, 2003	—	34,465,737	\$ 3,447	\$ 174,875,072	\$ (289,803)	\$ (131,194,686)	\$ 43,394,030

See accompanying notes to financial statements.

F-5

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS

	Year ended December 31,			For the Period July 22, 1980 (Inception) through December 31, 2003
	2003	2002	2001	
Cash flows from operating activities:				
Net loss	\$ (14,616,628)	\$ (29,359,051)	\$ (26,925,174)	\$ (131,194,686)
Adjustments to reconcile net loss to net cash flows used in operating activities:				
Depreciation and amortization	1,484,349	1,333,335	556,472	6,844,184
Realized gain on sale of short-term securities — available-for-sale	(3,765,752)	—	—	(3,862,502)
Write-down of short-term securities—available-for-sale	—	4,478,260	12,523,088	17,001,348
Compensation expense on issuance of common stock and partnership units	—	489,663	120,000	861,655
Compensation expense on issuance of options and warrants to purchase common stock or partnership units	471,460	148,254	120,000	1,302,067
Conversion of interest accrued to common stock	—	—	—	7,860
Acquired in-process research and development	—	—	—	19,545,028
(Increase) decrease in:				
Related party receivables and other current assets	316,960	805,612	(894,789)	(791,383)
Other assets	—	—	—	(29,847)
Net increase in accounts payable and accrued employee compensation	(1,371,141)	1,841,068	1,678,274	3,870,993
Net cash used in operating activities	(17,480,752)	(20,262,859)	(12,822,129)	(86,445,283)
Cash flows from investing activities:				
Purchase of property and equipment	(1,639,949)	(2,777,663)	(4,177,405)	(12,390,090)
Patent costs	(397,135)	(453,404)	(475,976)	(2,928,751)
Purchase of marketable securities	(44,421,888)	(19,095,394)	(8,114,802)	(71,632,084)
Sale of marketable securities	31,002,342	19,927,122	—	51,177,214
Acquisition costs	—	—	—	(2,377,616)
Net cash used in investing activities	(15,456,630)	(2,399,339)	(12,768,183)	(38,151,327)
Cash flows from financing activities:				
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants	35,077,334	21,977,710	10,761,250	137,506,962
Buyback of common stock pursuant to rescission offering	—	—	—	(288,795)
Withdrawal of partnership net assets	—	—	—	(176,642)
Issuance of convertible debt	—	—	—	80,000
Net cash provided by financing activities	35,077,334	21,977,710	10,761,250	137,121,525
Increase (decrease) in cash and cash equivalents	2,139,952	(684,488)	(14,829,062)	12,524,915
Cash and cash equivalents:				
Beginning of period	10,384,963	11,069,451	25,898,513	—
End of period	\$ 12,524,915	\$ 10,384,963	\$ 11,069,451	\$ 12,524,915

SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:

Change in unrealized gain (loss) on short-term securities-available-for-sale	\$ (1,019,759)	\$ (309,000)	\$ 12,722,370	\$ (289,803)
Issuance of common stock and warrants for services	\$ —	\$ —	\$ 370,000	370,000

AVI BIOPHARMA, INC.
(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND NATURE OF BUSINESS:

AVI BioPharma, Inc. (the Company or AVI) was incorporated in the State of Oregon on July 22, 1980. The mission of the Company is to develop and commercialize improved therapeutic products based upon antisense and cancer immunotherapy technology.

Through May 1993, the financial statements included the combined accounts of the Company and ANTI-GENE DEVELOPMENT GROUP, a limited partnership (AGDG or the Partnership) founded in 1981 and registered in the State of Oregon. Substantially all income generated and proceeds from the Partnership unit sales through that date have been paid to the Company under the terms of research and development contracts entered into by the Partnership and the Company. Significant transactions between the Company and the Partnership through that date have been eliminated.

In March 1993, the Company offered to all partners in the Partnership the opportunity to exchange their partnership units or warrants to purchase partnership units (unit warrants) for common stock or warrants to purchase common stock. Under the terms of the offer, which was completed May 1, 1993, each partner could elect to exchange each unit held or unit warrant held for 1,100 shares of common stock or warrants to purchase 1,100 shares of common stock of the Company, respectively. Total shares and warrants to purchase shares issued in the exchange offer were 1,632,950 and 381,700, respectively.

Effective May 19, 1993, the Company and the Partnership entered into a Technology Transfer Agreement wherein the Partnership conveyed all intellectual property then in its control to the Company. As part of the conveyance, the Company tendered to the Partnership for liquidation all partnership units received pursuant to the exchange offer and received a 49.37 percent undivided interest in the intellectual property. The Company then purchased the remaining undivided interest in the intellectual property for rights to payments of 4.05 percent of gross revenues in excess of \$200 million, from sales of products, which would, in the absence of the Technology Transfer Agreement, infringe a valid claim under any patent transferred to the Company. The Company also granted to the Partnership a royalty-bearing license to make, use and sell small quantities of product derived from the intellectual property for research purposes only.

In March 2000, the Company and AGDG amended the Technology Transfer Agreement to give to AGDG and Gene Tools LLC, related organizations, exclusive, non royalty-bearing rights to in vitro diagnostic applications of the intellectual property. In consideration for this amendment, Gene Tools paid the Company \$1 million and reduced the royalty that the Company would pay to AGDG under the Technology Transfer Agreement on future sales of therapeutic products from 4.05% to 3.00%.

The remaining net assets of the Partnership, \$176,642 of cash, were no longer combined with those of the Company in May 1993. Under the terms of the Technology Transfer Agreement, the Partnership ceased active sales of partnership units and income generating activities and no longer will enter into research and development contracts with the Company. The Partnership currently exists primarily for the purpose of collecting potential future payments from the Company as called for in the Technology Transfer Agreement.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include the valuation of marketable securities, carrying amount of property, plant and equipment, and valuation allowance for deferred income tax assets.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. The Company held cash equivalents of \$12,524,915 and \$10,384,963 as of December 31, 2003 and 2002, respectively which consist primarily of money market funds.

Short-Term Securities—Available-For-Sale

The Company accounts for its short-term securities in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115). The Company classifies its investment securities as available-for-sale and, accordingly, such investment securities are stated on the balance sheet at their fair market value. At December 31, 2003 and 2002, the Company's investments in marketable securities had gross unrealized gains (losses) of \$(289,803) and \$729,956, respectively. The unrealized difference between the cost and the fair market value of these securities has been reflected as a separate component of shareholders' equity. At December 31, 2003 and 2002, these short-term securities represent investments in commercial paper of \$24,719,804 and \$7,038,156, respectively. In 2002, short-term securities also included an investment in common stock of SuperGen, Inc., a related party, with a fair market value of \$1,625,608 at December 31, 2002. During the fourth quarter of 2003 the Company sold all of its investment in SuperGen, Inc and recognized a gain of \$3,765,752.

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, generally five years, using the straight-line method. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Expenditures for repairs and maintenance are expensed as incurred. Expenditures that increase the useful life or value are capitalized.

F-8

Amounts included in property and equipment are as follows:

As of December 31,	2003	2002
Lab equipment	\$ 3,864,847	\$ 3,388,902
Office equipment	490,352	435,172
Leasehold improvements	5,201,139	5,201,139
Construction in process	2,651,000	1,566,263
	12,207,338	10,591,476
Less accumulated depreciation	(5,198,912)	(4,007,186)
Property and equipment, net	\$ 7,008,426	\$ 6,584,290

Patent Costs

Patent costs consist primarily of legal and filing fees incurred to file patents on proprietary technology developed by the Company. Patent costs are amortized on a straight-line basis over the shorter of the estimated economic lives or the legal lives of the patents, generally 17 years.

Revenue Recognition

The Company records revenue from research contracts and grants as the services are performed and payment is reasonably assured. Upfront, nonrefundable fees and other fees associated with license and development arrangements are recognized as revenue ratably over the performance period. Revenue associated with performance milestones under license and development arrangements is recognized based upon the achievement of the milestones, as defined in the respective agreements. Fees received from SuperGen, Inc. pursuant to the Company's Avicine shared development arrangement are netted against research and development expense since the Company and SuperGen, Inc. share equally in all clinical development and FDA registration costs. To date revenue from license and development arrangements has not been significant.

Research and Development

Research and development (R&D) expenses include related salaries, contractor fees, materials, utilities and allocations of corporate costs. R&D expenses also consist of independent R&D costs and costs associated with collaborative development arrangements. In addition, the Company funds R&D at other companies and research institutions under agreements. Research and development costs are expensed as incurred.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered and settled.

F-9

Net Loss Per Share

Basic EPS is calculated using the weighted average number of common shares outstanding for the period and diluted EPS is computed using the weighted average number of common shares and dilutive common equivalent shares outstanding. Given that the Company is in a loss position, there is no difference between basic EPS and diluted EPS since the common stock equivalents would be antidilutive.

Year Ended December 31,	2003	2002	2001
Net loss	\$ (14,616,628)	\$ (29,359,051)	\$ (26,925,174)
Weighted average number of shares of common stock and common stock equivalents outstanding:			
Weighted average number of common shares outstanding for computing basic earnings per share	29,808,539	25,691,549	22,399,001
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*	*
Weighted average number of common shares outstanding for computing diluted earnings per share	29,808,539	25,691,549	22,399,001
Net loss per share - basic and diluted	\$ (0.49)	\$ (1.14)	\$ (1.20)

* The following common stock equivalents are excluded from earnings per share calculation as their effect would have been antidilutive:

Year Ended December 31,	2003	2002	2001
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Stock-based Compensation

The Financial Accounting Standards Board (FASB) has issued SFAS 123, which defines a fair value based method of accounting for an employee stock option and similar equity instruments and encourages all entities to adopt that method of accounting for all of their employee stock compensation plans. However, it also allows an entity to continue to measure compensation cost for those plans using the method of accounting prescribed by Accounting Principles Board Opinion No. 25 (APB 25). Entities electing to remain with the accounting in APB 25 must make pro forma disclosures of net income (loss) and earnings (loss) per share, as if the fair value based method of accounting defined in SFAS 123 had been adopted. In December 2002, the FASB issued SFAS 148 "Accounting for Stock-Based Compensation – Transition and Disclosure." SFAS 148 amends SFAS 123 for certain transition provisions for companies electing to adopt the fair value method and amends SFAS 123 for certain financial statement disclosures, including interim financial statements. The Company adopted SFAS 148 in December 2002. The Company has elected to account for its stock-based compensation plans (which are described in Note 3) under APB 25. The Company has computed, for pro forma disclosure purposes, the impact on net loss and net loss per share if the Company had accounted for its stock-based compensation plans in accordance with SFAS 123 as follows:

	For the Year Ended December 31,		
	2003	2002	2001
Net loss, as reported	\$ (14,616,628)	\$ (29,359,051)	\$ (26,925,174)
Deduct: Total stock-based employee compensation expense determined under fair value based method, for all awards not previously included in net loss	(3,436,587)	(2,177,358)	(2,447,783)
Pro forma net loss	<u>\$ (18,053,215)</u>	<u>\$ (31,536,409)</u>	<u>\$ (29,372,957)</u>
Basic and diluted net loss per share:			
As reported	\$ (0.49)	\$ (1.14)	\$ (1.20)
Pro forma	<u>\$ (0.61)</u>	<u>\$ (1.23)</u>	<u>\$ (1.31)</u>

No stock-based employee compensation is included in net loss for any of the periods presented since all of the options were granted at the fair market value of the Company's common stock on the date of grant. The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. Additional awards are anticipated in future years.

The value of all options granted during 2003, 2002 and 2001 using the Black-Scholes options pricing model as prescribed by SFAS 123 used the following weighted average assumptions for grants:

Year Ended December 31,	2003	2002	2001
Risk-free interest rate	2.13%	3.61%	5.56%
Expected dividend yield	0%	0%	0%
Expected lives	7.5 Years	7.5 Years	7.5 Years
Expected volatility	94%	88%	81%

Using the Black-Scholes methodology, the total value of options granted to employees during 2003, 2002 and 2001 was \$397,062, \$4,843,213 and \$476,638, respectively, which would be amortized on a pro forma basis over the vesting period of the options (typically four years). The weighted average fair value of options granted to employees during 2003, 2002 and 2001 was \$4.29, \$4.27 and \$5.14, respectively.

The Company records the fair value of stock options granted to non-employees in exchange for services in accordance with EITF 96-18 "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." The fair value of the options granted are expensed when the measurement date is known. The total fair value of the options granted to non-employees in 2003 was \$471,460.

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in the equity of an enterprise that results from transactions and other economic events of the period other than transactions with shareholders. The Company's only component of "other comprehensive income (loss)" is unrealized gain (loss) on short-term securities available-for-sale.

Recent Accounting Pronouncements

In August 2001, the FASB approved SFAS 143, "Accounting for Asset Retirement Obligations," which was effective beginning fiscal year 2003. SFAS 143 addresses the financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The adoption of SFAS 143 did not have a significant impact on the Company's financial condition or results of operations.

In July 2002, the FASB approved SFAS 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS 146 addresses the financial accounting and reporting for obligations associated with an exit activity, including restructuring, or with a disposal of long-lived assets. Exit activities include, but are not limited to, eliminating or reducing product lines, terminating employees and contracts and relocating plant facilities or personnel. SFAS 146 specifies that a company will record a liability for a cost associated with an exit or disposal activity only when that liability is incurred and can be measured at fair value. Therefore, commitment to an exit plan or a plan of disposal expresses only management's intended future actions and, therefore, does not meet the requirement for recognizing a liability and the related expense. SFAS 146 is effective prospectively for exit or disposal activities initiated after December 31, 2002, with earlier adoption encouraged. The adoption of SFAS 146 on January 1, 2003 did not have a material effect on the Company's financial position or results of operations.

In December 2003, the SEC issued Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104), which updates the previously issued revenue recognition guidance in SAB 101, based on the Emerging Issues Task Force Issue 00-21, Revenue Arrangements with Multiple Deliverables. If the deliverables in a sales arrangement constitute separate units of accounting according to the EITF's separation criteria, the revenue-recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting under the separation criteria, the revenue-recognition policy must be determined for the entire arrangement. The issuance of SAB 104 has not had any impact on the financial results of the Company.

3. LIQUIDITY:

The Company is in the development stage. Since its inception in 1980 through December 31, 2003, the Company has incurred losses of approximately \$131 million, substantially all of which resulted from expenditures related to research and development, general and administrative expenses, non-cash write-downs in 2002 of \$4,478,260 and in 2001 of \$12,523,088 on short-term securities—available-for-sale that had an other than temporary impairment as defined by SEC accounting rules and a one-time charge of \$19,545,028 for acquired in-process research and development reflecting the acquisition of ImmunoTherapy Corporation. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenues from product sales, the Company nevertheless expects to incur operating losses over the next several years.

F-12

The financial statements have been prepared assuming that the Company will continue as a going concern. The Company's ability to achieve a profitable level of operations in the future will depend in large part on its completing product development of its cancer vaccine, antisense and/or drug delivery products, obtaining regulatory approvals for such products and bringing these products to market. During the period required to develop these products, the Company will require substantial financing. There is no assurance that such financing will be available when needed or that the Company's planned products will be commercially successful. For 2004, the Company expects expenditures for operations, including collaborative efforts and GMP facilities to be approximately \$23 to \$25 million. The increase from 2003 expenditures is due to the increased use of an outside GMP manufacturing contractor. Expenditures for 2004 could increase if the Company undertakes additional collaborative efforts. However, if necessary, the Company's management has the ability to curtail expenditures because the vast majority of its costs are variable.

The likelihood of the long-term success of the Company must be considered in light of the expenses, difficulties and delays frequently encountered in the development and commercialization of new pharmaceutical products, competitive factors in the marketplace as well as the burdensome regulatory environment in which the Company operates. There can be no assurance that the Company will ever achieve significant revenues or profitable operations.

4. SHAREHOLDERS' EQUITY:

In May 2001, the Company entered into a license and development agreement with Medtronic, Inc. relating to the Company's antisense compounds which may have application in the treatment of vascular disease. The agreement provides for milestone payments and license royalties upon achievement of certain milestones or product sales. The Company also entered into a separate investment agreement with Medtronic for \$10,000,000 in cash in exchange for 1,408,451 shares of AVI common stock and a warrant to purchase 3,000,000 shares of AVI common stock. Closing of the transaction occurred during the second quarter of 2001. Pursuant to the investment agreement, Medtronic agrees to purchase 352,113 shares of common stock at \$7.10 per share and an additional \$7,500,000 of common stock based on the average trailing 5 days closing price preceding the commitment date. These stock purchases by Medtronic are subject to meeting certain technology milestones and any required regulatory or shareholder approvals.

In March 2002, the Company closed a private equity financing for net proceeds of \$21,321,000 with several institutional investors. The Company sold 3,070,671 shares of common stock at \$7.50 per share. Investors also received a warrant for the purchase of 614,139 common shares for \$10.50 per share. These warrants are immediately exercisable and expire in March 2006.

In May 2003, the Company closed a private equity financing for net proceeds of \$20,757,504 with several institutional investors. The Company sold 4,500,000 shares of common stock at \$5.00 per share. Investors also received a warrant for the purchase of 2,250,000 common shares for \$7.00 per share. These warrants are immediately exercisable and expire in May 2008. In connection with the equity financing, the Company issued 46,211 shares of common stock to the underwriters. The underwriters also received a warrant for the purchase of 315,000 common shares for \$7.00 per share. These warrants are immediately exercisable and expire in May 2008.

F-13

In December 2003, the Company closed a private equity financing for net proceeds of \$13,899,007 with several institutional investors. The Company sold 3,246,753 shares of common stock at \$4.62 per share. These investors received a warrant for the purchase of 1,623,377 common shares for \$4.62 per share. These warrants are immediately exercisable and expire on January 22, 2004. These investors also received a warrant for the purchase of 974,026 common shares for \$5.50 per share. These warrants are immediately exercisable and expire in December 2008. In connection with the equity financing, the placement agent received a warrant for the purchase of 340,909 common shares for \$5.50 per share. These warrants are immediately exercisable and expire in December 2008.

In 2000, the Board of Directors and the Company's shareholders approved the Employee Stock Purchase Plan under which the Company is authorized to sell up to 250,000 shares of common stock to its full-time employees, nearly all of whom are eligible to participate. Under the terms of the Plan, employees may elect every six months to have up to 10% of their compensation withheld to purchase the Company's common stock. The purchase price of the stock is 85% of the lower of the beginning-of-plan period or end-of-plan period market price of the Company's common stock. During 2003, employees elected to purchase a total of 30,467 shares of the Company's common stock at \$4.06 per share. During 2002, employees elected to purchase a total of 31,766 shares of the Company's common stock at \$4.74 per share. During 2001, employees elected to purchase 29,419 shares of the Company's common stock at \$5.61 per share.

The Company has two stock option plans, the 2002 Equity Incentive Plan and the 1997 Stock Option Plan (the Plans). The 2002 Plan provides for the issuance of incentive stock options to employees and nonqualified stock options, stock appreciation rights and bonus rights to employees, directors of the Company and consultants. The 1997 Plan provides for the assumption of the ImmunoTherapy Options under the Merger Agreement. The Company has

reserved 5,222,924 shares of common stock for issuance under the Plans. Options issued under the Plans generally vest ratably over four years and expire five to ten years from the date of grant.

A summary of the status of the Company's stock option plans and changes are presented in the following table:

For the Year Ended December 31,	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	3,668,581	\$ 5.68	2,857,049	\$ 5.82	2,855,296	\$ 5.73
Granted	212,500	5.07	1,195,338	4.99	92,756	6.80
Exercised	(79,640)	3.73	(82,301)	4.22	(79,649)	3.84
Canceled	(467,580)	6.34	(301,505)	4.69	(11,354)	3.98
Options outstanding at end of year	3,333,861	5.60	3,668,581	5.68	2,857,049	5.82
Exercisable at end of year	2,556,828	\$ 5.65	2,220,518	\$ 5.85	2,140,114	\$ 5.73

At December 31, 2003, 1,889,063 shares were available for future grant.

F-14

The following table summarizes information about stock options outstanding at December 31, 2003:

Exercise Price	Outstanding Shares at December 31, 2003	Weighted Average Remaining Contractual Life (Years)	Exercisable Options
\$ 0.04	11,500	1.93	11,500
3.31	54,090	3.08	54,090
3.50	233,547	3.62	233,547
3.69	31,000	4.57	31,000
3.75	33,334	4.91	33,334
3.81	15,000	4.64	15,000
3.97	132,768	3.13	132,768
4.16	25,000	9.28	—
4.25	20,000	4.98	—
4.28	5,000	4.10	—
4.55	30,000	4.62	—
4.75	33,111	1.99	29,111
4.87	20,000	9.01	—
4.89	10,000	9.02	—
4.95	99,158	1.23	99,158
5.00	4,000	0.95	4,000
5.15	7,500	9.92	—
5.35	745,800	8.93	248,600
5.53	40,000	6.93	—
5.75	503,000	6.01	503,000
5.88	45,000	9.38	—
5.94	10,000	0.37	10,000
6.00	66,668	2.70	66,668
6.38	235,000	3.44	235,000
6.63	510,000	4.11	510,000
6.65	73,334	8.37	28,334
6.69	100,000	3.69	100,000
6.88	132,000	6.62	117,000
7.19	33,334	6.59	25,001
8.10	29,717	2.89	29,717
8.13	25,000	3.84	25,000
8.63	10,000	7.50	5,000
10.00	10,000	1.41	10,000
	3,333,861		2,556,828

F-15

The Company has also issued warrants for the purchase of common stock in conjunction with financing and compensation arrangements. The 5,503,312, 614,139, and 3,000,000 warrants granted in 2003, 2002 and 2001, respectively, have not been considered in the fair value based method of accounting defined in SFAS 123 as such warrant grants related to the raising of additional equity. A summary of the status of the Company's warrants and changes are presented in the following table:

For the Year Ended December 31,	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Warrants outstanding at beginning of year	10,903,684	\$ 15.16	10,307,745	\$ 15.42	7,394,861	\$ 17.49
Granted	5,503,312	5.94	614,139	10.50	3,000,000	10.00

Exercised	—	—	(17,119)	9.62	(86,027)	4.04
Expired	(4,744,614)	13.43	(1,081)	8.70	(1,089)	8.70
Warrants outstanding at end of year	<u>11,662,382</u>	<u>11.20</u>	<u>10,903,684</u>	<u>15.16</u>	<u>10,307,745</u>	<u>15.42</u>
Exercisable at end of year	<u>9,996,504</u>	<u>\$ 7.13</u>	<u>9,187,806</u>	<u>\$ 11.47</u>	<u>8,541,867</u>	<u>\$ 11.55</u>

The following table summarizes information about warrants outstanding at December 31, 2003:

Exercise Price	Outstanding Warrants at December 31, 2003	Weighted Average Remaining Contractual Life (Years)	Exercisable Warrants
\$ 0.0003	16,667	No expiration date	16,667
1.14	1,000	No expiration date	1,000
4.03	414,286	0.97	414,286
4.62	2,237,516	0.66	2,237,516
5.50	1,314,935	4.94	1,314,935
7.00	2,565,000	4.34	2,565,000
8.70	297,100	1.58	297,100
10.00	3,150,000	2.42	3,150,000
35.63	1,665,878	6.25	—
	<u>11,662,382</u>		<u>9,996,504</u>

F-16

5. INCOME TAXES:

As of December 31, 2003 the Company has net operating loss carryforwards of approximately \$104,478,000, available to reduce future taxable income, which expire 2004 through 2023. Of this \$104,478,000, approximately \$4,150,000 relates to net operating losses assumed as part of the ImmunoTherapy Corporation acquisition. Utilization of these ImmunoTherapy Corporation net operating losses is limited to approximately \$1,200,000 per year. In addition, the Internal Revenue Code rules under Section 382 could limit the future use of the remaining \$100,328,000 in losses based on ownership changes and the value of the Company's stock. Approximately \$3,300,000 of the Company's carryforwards were generated as a result of deductions related to exercises of stock options. When utilized, this portion of the Company's carryforwards, as tax effected, will be accounted for as a direct increase to contributed capital rather than as a reduction of that year's provision for income taxes. The principal differences between net operating loss carryforwards for tax purposes and the accumulated deficit result from depreciation, amortization, investment write-downs, and treatment of research and development costs and deductions related to the exercise of stock options for income tax purposes.

The Company had net deferred tax assets of \$46,480,000 and \$41,344,000 at December 31, 2003 and 2002, primarily from net operating loss carryforwards. A valuation allowance was recorded to reduce the net deferred tax asset to zero because it is more likely than not the deferred tax asset will not be realized. The net change in the valuation allowance for deferred tax assets was an increase of approximately \$5,136,000, \$13,228,000 and \$10,769,000 for the years ended December 31, 2003, 2002 and 2001, respectively, mainly due to the increase in the net operating loss carryforwards, research and development tax credits and write-down of short-term securities.

An analysis of the deferred tax assets(liabilities) are as follows:

December 31,	2003	2002
Net operating loss carryforwards	\$ 40,747,000	\$ 30,471,000
Difference in depreciation and amortization	(727,000)	(671,000)
Investment in marketable securities	—	6,631,000
Research and development tax credits	6,460,000	4,913,000
	<u>46,480,000</u>	<u>41,344,000</u>
Valuation allowance	<u>(46,480,000)</u>	<u>(41,344,000)</u>
	<u>\$ —</u>	<u>\$ —</u>

6. RELATED PARTY TRANSACTIONS:

In April 2000, the Company entered into an alliance with SuperGen, Inc. for shared development and marketing rights for Avicine. Under the terms of the agreement, AVI and SuperGen, Inc. will equally share in future clinical development and FDA registration costs as well as in profits from product sales in the United States. Additionally, AVI may receive up to \$80 million from SuperGen, Inc. upon meeting commercialization benchmarks.

During the year ended December 31, 2003 and 2002, the Company paid Boston Healthcare Associates, Inc., of which director Andrew J. Ferrara is President, \$67,900 and \$73,563, respectively, for business development consulting services. The Company expects to pay Mr. Ferrara, or his firm, for additional consulting services that may be performed for the Company during 2004.

F-17

In June 2002, the Company loaned the chief executive officer of AVI \$500,000 under a one year term loan. The loan was secured by the chief executive officer's stock in AVI. Interest on the loan accrues at the rate of 4.75% per annum. This loan was made prior to the Sarbanes-Oxley Act, which prohibits loans to executives, and therefore is grandfathered in. On June 13, 2003, the loan to the Company's chief executive officer was repaid in full with accrued interest.

7. COMMITMENTS:

Lease Obligations

The Company leases office and laboratory facilities under various noncancelable operating leases through December 2007. Rent expense under these leases was \$912,000, \$946,000 and \$541,000 for the years ended December 31, 2003, 2002 and 2001, respectively, and \$4,565,000 for the period from July 22, 1980 through December 31, 2003.

At December 31, 2003, the aggregate noncancelable future minimum payments under these leases are as follows:

<u>Year ending December 31,</u>	
2004	\$ 882,000
2005	866,000
2006	892,000
2007	879,000
Total minimum lease payments	<u>\$ 3,519,000</u>

Royalty Obligations

The Company has license agreements for which it is obligated to pay the licensors a minimum annual royalty. Royalty payments under these agreements was \$175,000, \$175,000 and \$78,750 for the years ended December 31, 2003, 2002 and 2001, respectively, and \$608,750 for the period from July 22, 1980 through December 31, 2003.

At December 31, 2003, the aggregate future minimum royalty payments under these agreements are as follows:

<u>Year ending December 31,</u>	
2004	\$ 125,000
2005	125,000
2006	125,000
2007	125,000
2008	125,000
Thereafter	1,755,000
Total minimum royalty payments	<u>\$ 2,380,000</u>

F-18

8. FINANCIAL INFORMATION BY QUARTER (UNAUDITED):

<u>2003 for quarter ended</u>	<u>December 31</u>	<u>September 30</u>	<u>June 30</u>	<u>March 31</u>
Revenues from license fees, grants and research contracts	\$ 135,181	\$ 414,352	\$ 162,410	\$ 257,923
Operating expenses:				
Research and development	6,405,351	3,533,868	2,539,282	2,805,895
General and administrative	888,440	1,560,026	1,177,081	933,401
	<u>7,293,791</u>	<u>5,093,894</u>	<u>3,716,363</u>	<u>3,739,296</u>
Other income (loss):				
Interest income, net	296,630	75,887	56,025	62,556
Realized gain on sale of short-term securities—available-for-sale	3,765,752	—	—	—
Net loss	<u>\$ (3,096,228)</u>	<u>\$ (4,603,655)</u>	<u>\$ (3,497,928)</u>	<u>\$ (3,418,817)</u>
Net loss per share, basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.15)</u>	<u>\$ (0.12)</u>	<u>\$ (0.13)</u>
Shares used in per share calculations	<u>32,024,069</u>	<u>31,186,464</u>	<u>29,380,554</u>	<u>26,567,968</u>

<u>2002 for quarter ended</u>	<u>December 31</u>	<u>September 30</u>	<u>June 30</u>	<u>March 31</u>
Revenues from license fees, grants and research contracts	\$ 169,206	\$ 232,192	\$ 197,691	\$ 237,695
Operating expenses:				
Research and development	3,546,654	4,594,023	7,224,095	7,049,120
General and administrative	774,417	1,009,299	895,706	1,084,519
	<u>4,321,071</u>	<u>5,603,322</u>	<u>8,119,801</u>	<u>8,133,639</u>
Other income (loss):				
Interest income, net	158,031	111,169	111,207	79,851
Write-down of short-term securities—available-for-sale	—	(1,791,304)	(2,686,956)	—
Net loss	<u>\$ (3,993,834)</u>	<u>\$ (7,051,265)</u>	<u>\$ (10,497,859)</u>	<u>\$ (7,816,093)</u>
Net loss per share, basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.27)</u>	<u>\$ (0.40)</u>	<u>\$ (0.33)</u>
Shares used in per share calculations	<u>26,485,626</u>	<u>26,444,102</u>	<u>26,353,017</u>	<u>23,442,127</u>

9. SUBSEQUENT EVENTS:

On January 22, 2004, several institutional investors exercised warrants for the purchase of 1,623,377 shares of the Company's common stock at \$4.62 per share for gross proceeds of \$7.5 million. The warrants had been issued pursuant to a direct equity placement of the Company's common stock in December 2003 under the Company's effective shelf registration. Investors also received new five-year warrants to purchase 389,611 common shares for \$5.50 per share.

AVI BIOPHARMA, INC.

CODE OF BUSINESS CONDUCT AND ETHICS

Introduction.

We are committed to maintaining the highest standards of honest and ethical business conduct, including ensuring full, fair, accurate, timely and understandable disclosures in our public documents and reports, compliance with applicable laws, prompt internal reporting of violations of these standards and accountability for adherence to these standards. This Code of Business Conduct and Ethics (the “Code”) reflects the business practices and principles of behavior that support this commitment. We expect every employee, officer and director to read, understand and comply with the Code and its application to the performance of his or her business responsibilities. References in the Code to employees are intended to cover officers and, as applicable, directors, managers and supervisors as well as employees.

Officers, managers and other supervisors are expected to develop in employees a sense of commitment to the spirit, as well as the letter, of the Code. Supervisors are also expected to ensure that all agents and contractors conform to Code standards when working for or on behalf of AVI BioPharma, Inc. The compliance environment within each supervisor’s assigned area of responsibility will be a significant factor in evaluating the quality of that individual’s performance. In addition, any employee who makes an exemplary effort to implement and uphold the principles embodied in the Code will be recognized for that effort in his or her performance review. Nothing in the Code alters the employment at-will policy of AVI BioPharma, Inc.

The Code cannot possibly describe every practice or principle related to honest and ethical conduct. The Code addresses conduct that is particularly important to proper dealings with the people and entities with whom we interact, but reflects only a part of our commitment. The following additional policies of AVI BioPharma, Inc. supplement or amplify the Code in certain areas and should be read in conjunction with the Code: Insider Trading and Tipping Policy and Employee Manual.

Action by members of your immediate family, significant others or other persons who live in your household also may potentially result in ethical issues to the extent that they involve AVI BioPharma, Inc. business. For example, acceptance of inappropriate gifts by a family member from one of our suppliers could create a conflict of interest and result in a Code violation attributable to you. Consequently, in complying with the Code, you should consider not only your own conduct, but also that of your immediate family members, significant others and other persons who live in your household.

The integrity and reputation of AVI BioPharma, Inc. depends on the honesty, fairness and integrity brought to the job by each person associated with us. It is the responsibility of each employee to apply common sense, together with his or her own highest personal ethical standards, in making business decisions where there is no

1

stated guideline in the Code. Unyielding personal integrity is the foundation of corporate integrity.

YOU SHOULD NOT HESITATE TO ASK QUESTIONS ABOUT WHETHER ANY CONDUCT MAY VIOLATE THE CODE, VOICE CONCERNS OR CLARIFY GRAY AREAS. SECTION 16 BELOW DETAILS THE COMPLIANCE RESOURCES AVAILABLE TO YOU. IN ADDITION, YOU SHOULD BE ALERT TO POSSIBLE VIOLATIONS OF THE CODE BY OTHERS AND REPORT SUSPECTED VIOLATIONS, WITHOUT FEAR OF ANY FORM OF RETALIATION, AS FURTHER DESCRIBED IN SECTION 16. Violations of the Code will not be tolerated. Any employee who violates the standards in the Code may be subject to disciplinary action, up to and including termination of employment and, in appropriate cases, civil legal action or referral for criminal prosecution.

1. Legal Compliance.

Obeying the law, both in letter and in spirit, is the foundation of this Code. Our success depends upon each employee’s operating within legal guidelines and cooperating with local, national and international authorities. It is therefore essential that you understand the legal and regulatory requirements applicable to your business unit and area of responsibility. We hold periodic training sessions to ensure that all employees comply with the relevant laws, rules and regulations associated with their employment, including laws prohibiting insider trading (which are discussed in further detail in Section 4 below). While we do not expect you to memorize every detail of these laws, rules and regulations, we want you to be able to determine when to seek advice from others. If you do have a question in the area of legal compliance, it is important that you not hesitate to seek answers from your supervisor or the Corporate Responsibility Officer (see Section 16).

Disregard of the law will not be tolerated. Violation of domestic or foreign laws, rules and regulations may subject an individual, as well as AVI BioPharma, Inc., to civil and/or criminal penalties. You should be aware that conduct and records, including emails, are subject to internal and external audits, and to discovery by third parties in the event of a government investigation or civil litigation. It is in everyone’s best interests to know and comply with our legal and ethical obligations.

2. Misuse of Company Computer Equipment

You may not, while acting on behalf of AVI BioPharma, Inc. or while using our computing or communications equipment or facilities, either:

- access the internal computer system (also known as “hacking”) or other resource of another entity without express written authorization from the entity responsible for operating that resource; or
- commit any unlawful or illegal act, including harassment, libel, fraud, sending of unsolicited bulk email (also known as “spam”) in violation of applicable law, trafficking in contraband of any kind, or espionage.

2

If you receive authorization to access another entity's internal computer system or other resource, you must make a permanent record of that authorization so that it may be retrieved for future reference, and you may not exceed the scope of that authorization.

Unsolicited bulk email is regulated by law in a number of jurisdictions. If you intend to send unsolicited bulk email to persons outside of AVI BioPharma, Inc., either while acting on our behalf or using our computing or communications equipment or facilities, you should contact your supervisor or the Corporate Responsibility Officer for approval.

All data residing on or transmitted through our computing and communications facilities, including email and word processing documents, is the property of AVI BioPharma, Inc. and subject to inspection, retention and review by AVI BioPharma, Inc. in accordance with applicable law.

3. Environment Compliance

Federal law imposes criminal liability on any person or company that contaminates the environment with any hazardous substance that could cause injury to the community or environment. Violation of environmental laws can be a criminal offense and can involve monetary fines and imprisonment. We expect employees to comply with all applicable environmental laws.

It is our policy to conduct our business in an environmentally responsible way that minimizes environmental impacts. Our goal is to minimize and, if possible, eliminate the use of any substance or material that may cause environmental damage, reduce waste generation and dispose of all waste through safe and responsible methods, minimize environmental risks by employing safe technologies and operating procedures, and be prepared to respond appropriately to accidents and emergencies.

4. Insider Trading.

Employees who have access to confidential (or "inside") information are not permitted to use or share that information for stock trading purposes or for any other purpose except to conduct our business. All non-public information about AVI BioPharma, Inc. or about companies with which we do business is considered confidential information. To use material non-public information in connection with buying or selling securities, including "tipping" others who might make an investment decision on the basis of this information, is not only unethical, it is illegal. Employees must exercise the utmost care when handling material inside information. We have adopted a separate Insider Trading and Tipping Policy to which you are bound as a condition of your employment here. You should consult the Insider Trading and Tipping Policy for more specific information on the definition of "material inside information" and on buying and selling our securities or securities of companies with which we do business.

3

5. International Business Laws.

Our employees are expected to comply with the applicable laws in all countries to which they travel, in which they operate and where we otherwise do business, including laws prohibiting bribery, corruption or the conduct of business with specified individuals, companies or countries. The fact that in some countries certain laws are not enforced or that violation of those laws is not subject to public criticism will not be accepted as an excuse for noncompliance. In addition, we expect employees to comply with U.S. laws, rules and regulations governing the conduct of business by its citizens and corporations outside the U.S.

These U.S. laws, rules and regulations, which extend to all our activities outside the U.S., include:

- The Foreign Corrupt Practices Act, which prohibits directly or indirectly giving anything of value to a government official to obtain or retain business or favorable treatment, and requires the maintenance of accurate books of account, with all company transactions being properly recorded;
- U.S. Embargoes, which restrict or, in some cases, prohibit companies, their subsidiaries and their employees from doing business with certain other countries identified on a list that changes periodically (including currently, for example, Angola (partial), Burma (partial), Cuba, Iran, Iraq, North Korea, Sudan and Syria) or specific companies or individuals;
- Export Controls, which restrict travel to designated countries or prohibit or restrict the export of goods, services and technology to designated countries, denied persons or denied entities from the U.S., or the re-export of U.S. origin goods from the country of original destination to such designated countries, denied companies or denied entities; and
- Antiboycott Compliance, which prohibits U.S. companies from taking any action that has the effect of furthering or supporting a restrictive trade practice or boycott that is fostered or imposed by a foreign country against a country friendly to the U.S. or against any U.S. person.

If you have a question as to whether an activity is restricted or prohibited, seek assistance before taking any action, including giving any verbal assurances that might be regulated by international laws.

6. Conflicts of Interest.

A "conflict of interest" occurs when an individual's personal interest may interfere in any way with the performance of his or her duties or the best interests of AVI BioPharma, Inc. A conflicting personal interest could result from an expectation of personal gain now or in the future or from a need to satisfy a prior or concurrent personal obligation. We expect our employees to be free from influences that conflict

4

with the best interests of AVI BioPharma, Inc. Even the appearance of a conflict of interest where none actually exists can be damaging and should be avoided. Whether or not a conflict of interest exists or will exist can be unclear. Conflicts of interest are prohibited unless specifically authorized as

described below.

If you have any questions about a potential conflict or if you become aware of an actual or potential conflict, and you are not an officer or director of AVI BioPharma, Inc., you should discuss the matter with your supervisor or the Corporate Responsibility Officer (as further described in Section 16). Supervisors may not authorize conflict of interest matters without first seeking the approval of the Corporate Responsibility Officer and filing with the Corporate Responsibility Officer a written description of the authorized activity. If the supervisor is involved in the potential or actual conflict, you should discuss the matter directly with the Corporate Responsibility Officer. Officers and directors may seek authorization from the Audit Committee. Factors that may be considered in evaluating a potential conflict of interest are, among others:

- whether it may interfere with the employee's job performance, responsibilities or morale;
- whether the employee has access to confidential information;
- whether it may interfere with the job performance, responsibilities or morale of others within the organization;
- any potential adverse or beneficial impact on our business;
- any potential adverse or beneficial impact on our relationships with our customers or suppliers or other service providers;
- whether it would enhance or support a competitor's position;
- the extent to which it would result in financial or other benefit (direct or indirect) to the employee;
- the extent to which it would result in financial or other benefit (direct or indirect) to one of our customers, suppliers or other service providers; and
- the extent to which it would appear improper to an outside observer.

The following are examples of situations that may, depending on the facts and circumstances, involve conflicts of interests:

- **Employment by (including consulting for) or service on the board of a competitor, customer or supplier or other service provider.** Activity that enhances or supports the position of a competitor to the detriment of AVI BioPharma, Inc. is prohibited, including employment by or service on the board of a competitor. Employment by or service on the board of a customer

5

or supplier or other service provider is generally discouraged and you must seek authorization in advance if you plan to take such action.

- **Owning, directly or indirectly, a significant financial interest in any entity that does business, seeks to do business or competes with us.** In addition to the factors described above, persons evaluating ownership for conflicts of interest will consider the size and nature of the investment; the nature of the relationship between the other entity and AVI BioPharma, Inc.; the employee's access to confidential information and the employee's ability to influence AVI BioPharma, Inc. decisions. If you would like to acquire a financial interest of that kind, you must seek approval in advance.
- **Soliciting or accepting gifts, favors, loans or preferential treatment from any person or entity that does business or seeks to do business with us.** See Section 10 for further discussion of the issues involved in this type of conflict.
- **Soliciting contributions to any charity or for any political candidate from any person or entity that does business or seeks to do business with us.**
- **Taking personal advantage of corporate opportunities.** See Section 7 for further discussion of the issues involved in this type of conflict.
- **Moonlighting without permission.**
- **Conducting our business transactions with your family member, significant other or person who shares your household or a business in which you have a significant financial interest.** Material related-party transactions approved by the Audit Committee and involving any executive officer or director will be publicly disclosed as required by applicable laws and regulations.
- **Exercising supervisory or other authority on behalf of AVI BioPharma, Inc. over a co-worker who is also a family member.** The employee's supervisor and/or the Corporate Responsibility Officer will consult with the Human Resources department to assess the advisability of reassignment.

Loans to, or guarantees of obligations of, employees or their family members by AVI BioPharma, Inc. could constitute an improper personal benefit to the recipients of these loans or guarantees, depending on the facts and circumstances. Some loans are expressly prohibited by law and applicable law requires that our Board of Directors approve all loans and guarantees to employees. As a result, all loans and guarantees by or to AVI BioPharma, Inc. must be approved in advance by the Audit Committee.

6

You may not take personal advantage of opportunities that are presented to you or discovered by you as a result of your position with us or through your use of corporate property or information, unless authorized by your supervisor, the Corporate Responsibility Officer or the Audit Committee, as described in Section 6. Even opportunities that are acquired privately by you may be questionable if they are related to our existing or proposed lines of business. Participation in an investment or outside business opportunity that is related to our existing or proposed lines of business must be pre-approved. You cannot use your position with us or corporate property or information for improper personal gain, nor can you compete with us in any way.

8. Maintenance of Corporate Books, Records, Documents and Accounts; Financial Integrity; Public Reporting.

The integrity of our records and public disclosure depends on the validity, accuracy and completeness of the information supporting the entries to our books of account. Therefore, our corporate and business records should be completed accurately and honestly. The making of false or misleading entries, whether they relate to financial results or test results, is strictly prohibited. Our records serve as a basis for managing our business and are important in meeting our obligations to customers, suppliers, creditors, employees and others with whom we do business. As a result, it is important that our books, records and accounts accurately and fairly reflect, in reasonable detail, our assets, liabilities, revenues, costs and expenses, as well as all transactions and changes in assets and liabilities. We require that:

- no entry be made in our books and records that intentionally hides or disguises the nature of any transaction or of any of our liabilities, or misclassifies any transactions as to accounts or accounting periods;
- transactions be supported by appropriate documentation;
- the terms of sales and other commercial transactions be reflected accurately in the documentation for those transactions and all such documentation be reflected accurately in our books and records;
- employees comply with our system of internal controls; and
- no cash or other assets be maintained for any purpose in any unrecorded or “off-the-books” fund.

Our accounting records are also relied upon to produce reports for our management, stockholders and creditors, as well as for governmental agencies. In particular, we rely upon our accounting and other business and corporate records in preparing the periodic and current reports that we file with the SEC. These reports must provide full, fair, accurate, timely and understandable disclosure and fairly present our financial condition and results of operations. Employees who collect, provide or analyze

7

information for or otherwise contribute in any way in preparing or verifying these reports should strive to ensure that our financial disclosure is accurate and transparent and that our reports contain all of the information about AVI BioPharma, Inc. that would be important to enable stockholders and potential investors to assess the soundness and risks of our business and finances and the quality and integrity of our accounting and disclosures. In addition:

- no employee may take or authorize any action that would cause our financial records or financial disclosure to fail to comply with generally accepted accounting principles, the rules and regulations of the SEC or other applicable laws, rules and regulations;
- all employees must cooperate fully with our Accounting Department, as well as our independent public accountants and counsel, respond to their questions with candor and provide them with complete and accurate information to help ensure that our books and records, as well as our reports filed with the SEC, are accurate and complete; and
- no employee should knowingly make (or cause or encourage any other person to make) any false or misleading statement in any of our reports filed with the SEC or knowingly omit (or cause or encourage any other person to omit) any information necessary to make the disclosure in any of our reports accurate in all material respects.

Any employee who becomes aware of any departure from these standards has a responsibility to report his or her knowledge promptly to a supervisor, the Corporate Responsibility Officer or one of the other compliance resources described in Section 16.

9. Fair Dealing.

We strive to outperform our competition fairly and honestly. Advantages over our competitors are to be obtained through superior performance of our products and services, not through unethical or illegal business practices. Acquiring proprietary information from others through improper means, possessing trade secret information that was improperly obtained, or inducing improper disclosure of confidential information from past or present employees of other companies is prohibited, even if motivated by an intention to advance our interests. If information is obtained by mistake that may constitute a trade secret or other confidential information of another business, or if you have any questions about the legality of proposed information gathering, you must consult your supervisor or the Corporate Responsibility Officer, as further described in Section 16.

You are expected to deal fairly with our customers, suppliers, employees and anyone else with whom you have contact in the course of performing your job. No employee may take unfair advantage of anyone through misuse of confidential information, misrepresentation of material facts or any other unfair dealing practice.

8

Employees involved in procurement have a special responsibility to adhere to principles of fair competition in the purchase of products and services by selecting suppliers based exclusively on normal commercial considerations, such as quality, cost, availability, service and reputation, and not on the receipt of special favors.

10. Gifts and Entertainment.

Business entertainment and gifts are meant to create goodwill and sound working relationships and not to gain improper advantage with customers or facilitate approvals from government officials. Unless express permission is received from a supervisor, the Corporate Responsibility Officer or the Audit Committee, entertainment and gifts cannot be offered, provided or accepted by any employee unless consistent with customary business practices and not (a) excessive in value, (b) in cash, (c) susceptible of being construed as a bribe or kickback or (d) in violation of any laws. This principle applies to our transactions everywhere in the world, even where the practice is widely considered “a way of doing business.” Under some statutes, such as the U.S. Foreign Corrupt Practices Act (further described in Section 5), giving anything of value to a government official to obtain or retain business or favorable treatment is a criminal act subject to prosecution and conviction. Discuss with your supervisor or the Corporate Responsibility Officer any proposed entertainment or gifts if you are uncertain about their appropriateness.

11. Antitrust.

Antitrust laws are designed to protect the competitive process. These laws generally prohibit:

- agreements, formal or informal, with competitors that harm competition or customers, including price fixing and allocations of customers, territories or contracts;
- agreements, formal or informal, that establish or fix the price at which a customer may resell a product; and
- the acquisition or maintenance of a monopoly or attempted monopoly through anti-competitive conduct.

Certain kinds of information, such as pricing, production and inventory, should not be exchanged with competitors, regardless of how innocent or casual the exchange may be and regardless of the setting, whether business or social.

Understanding the requirements of antitrust and unfair competition laws of the various jurisdictions where we do business can be difficult, and you are urged to seek assistance from your supervisor or the Corporate Responsibility Officer whenever you have a question relating to these laws.

12. Protection and Proper Use of Company Assets.

All employees are expected to protect our assets and ensure their efficient use. Theft, carelessness and waste have a direct impact on our profitability. Our property, such as laboratory equipment, office equipment, office supplies and computer equipment, are expected to be used only for legitimate business purposes, although incidental personal use may be permitted. Employees should be mindful of the fact that we retain the right to access, review, monitor and disclose any information transmitted, received or stored using our electronic equipment, with or without an employee's or third party's knowledge, consent or approval. Any misuse or suspected misuse of our assets must be immediately reported to your supervisor or the Corporate Responsibility Officer.

13. Confidentiality.

One of our most important assets is our confidential information. Employees who have received or have access to confidential information should take care to keep this information confidential. Confidential information may include business, marketing and service plans, financial information, product architecture, source codes, [engineering and manufacturing ideas,] designs, databases, customer lists, pricing strategies, personnel data, personally identifiable information pertaining to our employees, customers or other individuals (including, for example, names, addresses, telephone numbers and social security numbers), and similar types of information provided to us by our customers, suppliers and partners. This information may be protected by patent, trademark, copyright and trade secret laws.

Except when disclosure is authorized or legally mandated, you must not share our or our suppliers' or customers' confidential information with third parties or others within AVI BioPharma, Inc. who have no legitimate business purpose for receiving that information. Doing so would constitute a violation of the employment agreement that you signed upon joining us. Unauthorized use or distribution of this information could also be illegal and result in civil liability and/or criminal penalties.

You should also take care not to inadvertently disclose confidential information. Materials that contain confidential information, such as memos, notebooks, computer disks and laptop computers should be stored securely. Unauthorized posting or discussion of any information concerning our business, information or prospects on the Internet is prohibited. You may not discuss our business, information or prospects in any “chat room,” regardless of whether you use your own name or a pseudonym. Be cautious when discussing sensitive information in public places like elevators, airports, restaurants and “quasi-public” areas within AVI BioPharma, Inc., such as cafeterias. All AVI BioPharma, Inc. emails, voicemails and other communications are presumed confidential and should not be forwarded or otherwise disseminated outside of AVI BioPharma, Inc., except where required for legitimate business purposes.

In addition to the above responsibilities, if you are handling information protected by any privacy policy published by us, then you must handle that information solely in accordance with the applicable policy.

14. Media/Public Discussions.

It is our policy to disclose material information concerning AVI BioPharma, Inc. to the public only through specific limited channels to avoid inappropriate publicity and to ensure that all those with an interest in the company will have equal access to information. All inquiries or calls from the press and financial analysts should be referred to the CEO, President or the investor relations department. We have designated our CEO, President and CFO as our official spokespersons for financial matters. We have designated our CEO and President as our official spokespersons for marketing, technical and other

related information. Unless a specific exception has been made by the CEO, President or CFO, these designees are the only people who may communicate with the press on behalf of AVI BioPharma, Inc.

15. Waivers.

Any waiver of this Code for executive officers (including, where required by applicable laws, our principal executive officer, principal financial officer, principal accounting officer or controller (or persons performing similar functions)) or directors may be authorized only by our Board of Directors or a committee of the Board and will be disclosed to stockholders as required by applicable laws, rules and regulations.

16. Compliance Standards and Procedures.

Compliance Resources

To facilitate compliance with this Code, we have implemented a program of Code awareness, training and review. We have established the position of Corporate Responsibility Officer to oversee this program. The Corporate Responsibility Officer is a person to whom you can address any questions or concerns. The Corporate Responsibility Officer, Alan P. Timmins, can be reached at (503) 227-0554 or via email at ethics@avibio.com. In addition to fielding questions or concerns with respect to potential violations of this Code, the Corporate Responsibility Officer is responsible for:

- investigating possible violations of the Code;
- training new employees in Code policies;
- conducting annual training sessions to refresh employees' familiarity with the Code;
- distributing copies of the Code annually to each employee with a reminder that each employee is responsible for reading, understanding and complying with the Code;
- updating the Code as needed and alerting employees to any updates, with appropriate approval of the Audit Committee of the Board of Directors, to reflect changes in the law, AVI BioPharma, Inc. operations and in

11

recognized best practices, and to reflect AVI BioPharma, Inc. experience; and

- otherwise promoting an atmosphere of responsible and ethical conduct.

Your most immediate resource for any matter related to the Code is your supervisor. He or she may have the information you need, or may be able to refer the question to another appropriate source. There may, however, be times when you prefer not to go to your supervisor. In these instances, you should feel free to discuss your concern with the Corporate Responsibility Officer.

In order to make reporting violations as simple and accessible as possible, we have established a website and toll-free number for employees to report instances of observed or suspected violations of this Code. AVI BioPharma, Inc. has contracted with Ethicspoint, an outside company, to handle such reports. Reports using either the website or toll-free number may be made on an anonymous basis; however, the process of obtaining follow-up and clarifying information will be made much more effective if you identify yourself. The toll-free number is 1-800-729-0021, and the website is www.ethicspoint.com. Both are available 24 hours per day, 7 days per week.

Clarifying Questions and Concerns; Reporting Possible Violations

If you encounter a situation or are considering a course of action and its appropriateness is unclear, discuss the matter promptly with your supervisor or the Corporate Responsibility Officer; even the appearance of impropriety can be very damaging and should be avoided.

If you are aware of a suspected or actual violation of Code standards by others, you have a responsibility to report it. You are expected to promptly provide a compliance resource with a specific description of the violation that you believe has occurred, including any information you have about the persons involved and the time of the violation. Whether you choose to speak with your supervisor or the Corporate Responsibility Officer, you should do so without fear of any form of retaliation. We will take prompt disciplinary action against any employee who retaliates against you, up to and including termination of employment.

Supervisors must promptly report any complaints or observations of Code violations to the Corporate Responsibility Officer. The Corporate Responsibility Officer will investigate all reported possible Code violations promptly and with the highest degree of confidentiality that is possible under the specific circumstances. Your cooperation in the investigation will be expected. As needed, the Corporate Responsibility Officer will consult with Davis Wright Tremaine LLP, the Human Resources department and/or the Audit Committee of the Board of Directors

If the investigation indicates that a violation of the Code has probably occurred, we will take such action as we believe to be appropriate under the circumstances. If we

12

determine that an employee is responsible for a Code violation, he or she will be subject to disciplinary action up to, and including, termination of employment and, in appropriate cases, civil action or referral for criminal prosecution. Appropriate action may also be taken to deter any future Code violations.

13



INDEPENDENT AUDITORS CONSENT

The Board of Directors
AVI BioPharma, Inc.,

We consent to the incorporation by reference in the registration statement Nos. 333-86778, 333-105412, 333-109015, 333-68502, 333-45888, 333-93135 and 333-86039 on Forms S-3 and Nos. 333-101826, 333-49996, 333-49994 and 333-34047 on Forms S-8 of AVI BioPharma, Inc. of our report dated February 10, 2004, with respect to the balance sheets of AVI BioPharma, Inc. as of December 31, 2003 and 2002 and the related statements of operations, stockholders' equity and cash flows for the years then ended, which report appears in the December 31, 2003 annual report on Form 10-K of AVI BioPharma, Inc.

/s/ KPMG LLP

Portland, Oregon,
March 15, 2004

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Denis R. Burger, certify that:

1. I have reviewed this quarterly report on Form 10-K of AVI BioPharma, Inc. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2004

By: /s/ Denis R. Burger
Denis R. Burger,
Chief Executive Officer and Chairman
of the Board
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark M. Webber, certify that:

1. I have reviewed this quarterly report on Form 10-K of AVI BioPharma, Inc. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2004

By:

/s/ Mark M. Webber
Mark M. Webber,
Chief Financial Officer and Chief
Information Officer
(Principal Financial and Accounting Officer)

CERTIFICATION OF CEO AND CFO PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of AVI BioPharma, Inc. (the "Company") on Form 10-K for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Denis R. Burger, as Chief Executive Officer of the Company, and Mark M. Webber, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge,:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Denis R. Burger

Denis R. Burger
Chairman and Chief Executive Officer
AVI BioPharma, Inc.
March 15, 2004

/s/ Mark M. Webber

Mark M. Webber
Chief Financial Officer and Chief Information Officer
AVI BioPharma, Inc.
March 15, 2004

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

See also the certification pursuant to Sec. 302 of the Sarbanes-Oxley Act of 2002, which is also attached to this Report.